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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Report

Report of the Workgroup on E-Pedigree

William Powers, Public Member, Chair
David Fong, Pharm.D.
Stan Goldenberg, RP.h.

Report of March 16, 2006

FOR ACTION

ACTION ITEM 1

That the Board of Pharmacy consider the requests to delay implementation of the electronic pedigree until January 1, 2008.

Discussion
In 2004, the Board of Pharmacy sponsored SB 1307 (Figueroa), which was signed by Governor Schwarzenegger and became law on January 1, 2005. The bill made various changes to the wholesaler requirements and distribution of dangerous drugs. Most of the changes strengthened and clarified the requirements for the distribution of dangerous drugs and dangerous devices in California.

Over the last year, the Enforcement Committee has been monitoring the implementation of this legislation especially the implementation of the pedigree requirement. The bill requires an electronic pedigree by January 1, 2007 and gives the board the authority to extend the compliance date to January 1, 2008. The Legislature may extend the compliance date for pharmacies to January 1, 2009. The purpose of the pedigree is to maintain the integrity of the pharmaceutical supply chain in the United States. At the February board meeting, the board agreed to form a workgroup on E-Pedigree, which held its first meeting on March 16, 2006 and was attended by over 60 stakeholders.

At this first workgroup meeting, there were several presentations. Supervising Inspector Judi Nurse presented on California's requirements for electronic pedigree. Mike Rose from Johnson and Johnson and Ron Bone from McKesson as Co-Chairs of the EPC global Healthcare and Life Sciences Business and Action Group presented on the state of electronic pedigree and Radio Frequency Identification (RFID) technology standards. Walt Slijepcevich of Pfizer presented on Pfizer's Viagra RFID authentication pilot program and Bob Dufour from Wal-Mart Stores gave an overview of its experience

with RFID. For this meeting, Robert Celeste of EPCglobal will give a presentation on the status of standards for electronic pedigree. **(Attachment A)**

To address questions regarding the implementation of the e-pedigree requirement, a question and answer document was prepared and provided to all interested parties. Based on the discussion at December Enforcement Committee meeting and other questions that were subsequently submitted, the document was revised and provided to the workgroup for discussion. Questions with a shaded background identified those questions that were new or that had been revised from the original December document. The document was marked "draft" because it is a work in progress. **(Attachment B)**

Of most concern to the many that attended this first workgroup meeting was the implementation date of January 1, 2007. Business and Professions Code § 4034 and 4163 become operative on January 1, 2007, and as of that date prohibit any wholesale sales, trades, or transfers of prescription drugs, or any acquisitions of prescription drugs, absent a pedigree recording and accompanying the transaction. Pursuant to Sections 4163.5 and 4163.6, this prohibition and/or the requirement of a pedigree may be delayed by the Board of Pharmacy until January 1, 2008, upon a demonstration of need by the industry, and the by the Legislature (for pharmacies) until January 1, 2009.

The board has received requests for delay in implementation. At the September 2005 Enforcement Committee meeting, Lew Kontnik, Director of Brand Protection/Business Continuity for Amgen demonstrated the challenges that Amgen has encountered in developing an electronic pedigree and the implementation of RFID to track its liquid products. At the conclusion of the presentation, Mr. Kontnik stated that it his company's position that it will be extremely difficult to meet the January 1, 2007 deadline.

In addition, the board has received letters from the Food Marketing Institute (FMI), National Association of Chain Drug Stores (NACDS), Biogen Idec seeking a delay in implementation to January 1, 2008, because of concerns that it is an unrealistic compliance date for the entire pharmaceutical supply chain, from manufacturers to pharmacies to implement and comply with the requirements of an electronic pedigree.

It was expressed that twelve states, including California, have adopted legislation requiring pedigrees for prescription drugs. However, no state has imposed requirements as broad and far-reaching as California. It was suggested that California consider as the other states have a provision that recognizes a "normal distribution channel." "Normal distribution channel" means a chain of custody during distribution of a prescription drug that goes from a manufacturer to a wholesaler distributor to a pharmacy to a patient or a chain of custody for a drug that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intercompany pharmacy to a patient. Direct sales of a prescription drugs by a manufacturer to a pharmacy or a chain pharmacy warehouse are within the normal distribution channel. Therefore, a prescription drug that is distributed through the "normal distribution channel" would not be required to have a pedigree.

It was noted that the "normal distribution channel" concept was considered during the legislative process, but was not accepted by the board. The problems with a "normal distribution channel" or "authorized distributor" approach include the difficulty of monitoring and enforcing such relationships. Whereas it is possible for board inspectors and staff to identify and verify an e-pedigree, they are not experts in contract law and able to reliably analyze contractual relationships between manufacturers,

wholesalers, and pharmacies, such as would be necessary to verify claimed exemptions from e-pedigree requirements based on "normal distribution channel" or "authorized distributor" relationships. Moreover, where status as a "normal distribution channel" or "authorized distributor" depends on private-party designations as such, the board lacks the ability to effectively monitor such designations. These relationships can change without notice, and often out of the view of the board. And furthermore, adopting a "normal distribution channel" or "authorized distributor" approach would presumably exempt a huge number of transactions from being part of the e-pedigree tracking system, which is inimical to the intent of the statute. This would take those transactions out of the verifiable e-pedigree domain, and increase the temptation for individuals, including even the employees of those "authorized distributors," to take advantage of this lack of oversight. The risk is too great. The e-pedigree is a far more reliable method of tracking the flow of drugs.

Concern was also expressed regarding the impact of the pedigree requirement may have on the generic prescription drug market. The majority of generic drug manufacturers operate on very slim profit margins. Consequently, they may not have the financial resources to implement electronic pedigree technology for their products in the next few months.

Other alternatives included establishing a list of the most susceptible prescription drugs and require a pedigree for only those drugs on the list. Provide exemptions to wholesalers that distribute incidental shipments of prescription drugs into California and exempt Third Party Logistics Providers from licensure as wholesalers.

It was also noted that the delay on the effective date of the pedigree provisions in the federal Prescription Drug Marketing Act (PDMA) expires December 2006. In February 2006, the federal Food and Drug Administration (FDA) held a Counterfeit Drug Task Force Public Workshop to receive comments. It was reported that the task force for the Anti-Counterfeiting initiative plans to issue its final report to the Commissioner in May. During this workshop, it was suggested to the FDA that it create uniform standards for pedigree implementation so that an interoperable system could be created to assist the states. A delay by the board would give the FDA time to create additional guidance for states and/or modify the PDMA.

The Enforcement Committee members of the E-Pedigree Workgroup acknowledged the tremendous amount work that the industry has done nationwide to implement the electronic pedigree requirement and while much of the discussion focused on why compliance could not be met by January 1,2007, the committee asked the stakeholders to set forth how compliance will be achieved and the milestones that will be used to reach this goal. To consider the requests for delay in implementation at the April board meeting, the committee requested that the stakeholders submit with their extension requests implementation milestones to the executive officer by April 1, 2006. Many stakeholders expressed concern that they could not meet the 2007 date because they are dependent upon the actions of others in the distribution chain.

In addition to the previous requests, the board has received two more letters requesting a delay in implementation. The first letter is from the Generic Pharmaceutical Association (GPhA) stating its position that more time is necessary to ensure that a pedigree process can be properly and effectively implemented. This is because many generic companies manufacturer numerous products, which is far more than brand companies, thus, making it a greater burden on the generic manufacturer to implement a pedigree program.

The National Association of Chain Drug Stores (NACDS) and the California Retailers Association (CRA) submitted its second request for a delay based on the direction of the workgroup. They explained that their members would be participating in the newly formed coalition of community pharmacies, manufacturers and distributors to work on the California electronic pedigree implementation plans and milestones. The Health Distributors Management Association (HDMA) and its member wholesalers are organizing this coalition. It is anticipated that the first meeting will be April 25, 2006. They also noted that NACDS members have been actively involved with EPCglobal. NACDS commented that it is working diligently within EPCglobal to research and potentially develop an RFID enabled electronic pedigree system. NACDS stated that it needs more time to ensure that an electronic pedigree can be created that is interoperable among technology vendors and the various states and other stakeholders.

In addition, NACDS and CRA commented that the board should require that all software vendors that offer a solution for the California e-pedigree requirement certify that their software is interoperable. Once there is interoperable software, community pharmacies can begin to pilot and validate the systems to assure that the software can work in real-time so not to affect productivity. They anticipate that the process from the time that interoperable software is available through the phases of testing, validation and deployment across all pharmacies in California, could take as long as two years.

NACDS and CRA offered solutions in the interim such as not to require a pedigree for prescription drugs that are passed through the "normal distribution channel," alerting and educating health care professionals in a timely manner about counterfeit drug products, and enforcing current law against drug importation by non-manufacturers. **(Attachment C)**

Based on concern by the industry that they will be unable to meet the January 1, 2007 implementation date for the pedigree requirement, the Senate Business and Professions Committee has introduced SB 1476 to extend the implementation date to January 1, 2008. This bill also extends the board's sunset provision to January 1, 2010.

NO ACTION

Enforcement Committee – Workgroup on E-Pedigree Meeting Summary of March 16, 2006 (Attachment D)

Report on Enforcement Actions (Attachment E)

Quarterly Status Report on Committee Strategic Objectives for 2005/2006 (Attachment F)

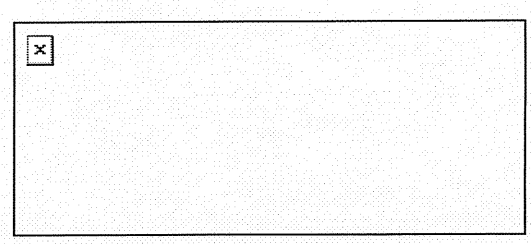
ATTACHMENT A

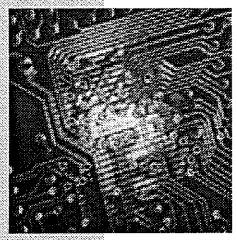
California Board of Pharmacy

State of Pedigree and EPC/RFID Standards

Mike Rose – Johnson and Johnson

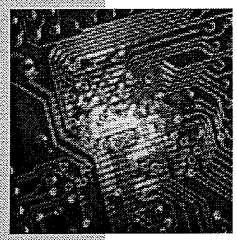
Ron Bone – McKesson Pharmaceutical Supply





EPCglobal Community

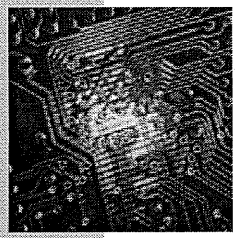
Established	**Nov-2003**
Mandate	**- Develop user-driven technical standards for EPC** **- Support adoption and implementation of EPC** **- Leverage 30+ year expertise in managing globally unique numbers (UPC and barcode)**
Principles	**- Not for profit standards organization** **- User driven and governed (all supply chain roles)** **- Public policy and regulatory support** **- Direct, practical support for industry initiatives** **- Key value driver is standardized data exchange** **- Global implementation support (103 offices)** **- Committed to working with government, industry associations, other standards bodies** **- Support large, medium and small companies**
Standards Work	**1,600+ global participants**
Subscribers	**800+ global subscribers**



EPCglobal Community

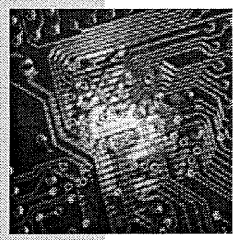
	Global Membership			
	Jun-04	Dec-05	Current %	% Increase
Asia	21	158	19.6%	752.4%
North America	132	498	61.9%	377.3%
Europe	36	124	15.4%	344.4%
Middle East and Africa	2	8	1.0%	400.0%
Latin America	0	17	2.1%	n/a
	191	805		421.5%

- 30 of top 40 global **pharmaceutical manufacturers**, 16 of top 20 US manufacturers
- 3 of top 4 **retail pharmacies** and 4 of top 6 **supermarket pharmacies** are part of EPCglobal (20,000 locations in total)
- 4 of top 5 **medical devices** companies are current subscribers



EPC in the Healthcare Industry

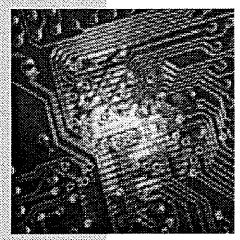
- EPCglobal Healthcare Action Group formed in 2004
  - **US members represent 38 of 40 largest manufacturers**
  - **3 largest distributors**
  - **Major retailers**
  - **Formed in association with HDMA, NACDS and others**
- Active participation in all key supply chain roles
  - **Manufacturers, Distributors, Retailers, Hospitals**
- Focused on addressing critical needs:
  - **Pedigree Management (including a Pedigree Messaging Standard)**
  - **Air Interface Standard for item level tagging**
  - **Serialization (the format of the EPC on the tag)**
  - **Decommissioning of tags**
  - **Network Security**
- EPCglobal helped form and supports the Unified Pedigree Coalition



Safe and Secure Supply Chain

EPC/RFID

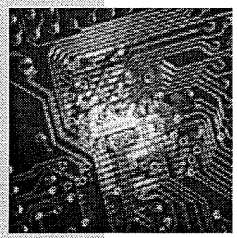
- Read and authenticate shipments with no "line of sight" needed
  - **Confirming inbound receipts of item level product**
  - **Identifying expired items w/o handling each item**
  - **Receipt of pallets and cases with out disassembly**
  - **Reduced physical handling = reduced risk/increased security**
- EPC takes advantage of best practices for data sharing
  - **Distributed data (data is held by owner)**
  - **Lower cost to supply chain**
- Industry actively moving towards standardization
  - **Item Level Requirements identified**
  - **EPCglobal Technology Demonstration March 23-24**
  - **Development of new/modified standard**



Safe and Secure Supply Chain

EPC and Public/Private Leadership

- Current EPC implementations by global leaders indicate long-term commitment
- RFID has the capability to solve critical regulatory issues
- Physics and standards challenges are being addressed
  - **Not all products are RFID candidates at this time – Biologics, proteins, metal & glass**
- Tag and reader prices are coming down
- Pilots are underway and learnings are contributing to standards efforts



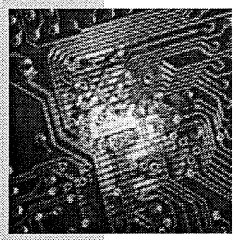
ePedigree and RFID Challenges

Industry Challenges:

- **Data Sharing Issues**
- **Non-serialized Items**
- **Patient Privacy**
- **Public Policy**
- **Regulatory Considerations**
- **Cost/Benefits Differ by Stakeholder**
- **End-to-End Supply Chain Implementation Essential for Mass Adoption**
- **Lack of Universal Pedigree Agreement**

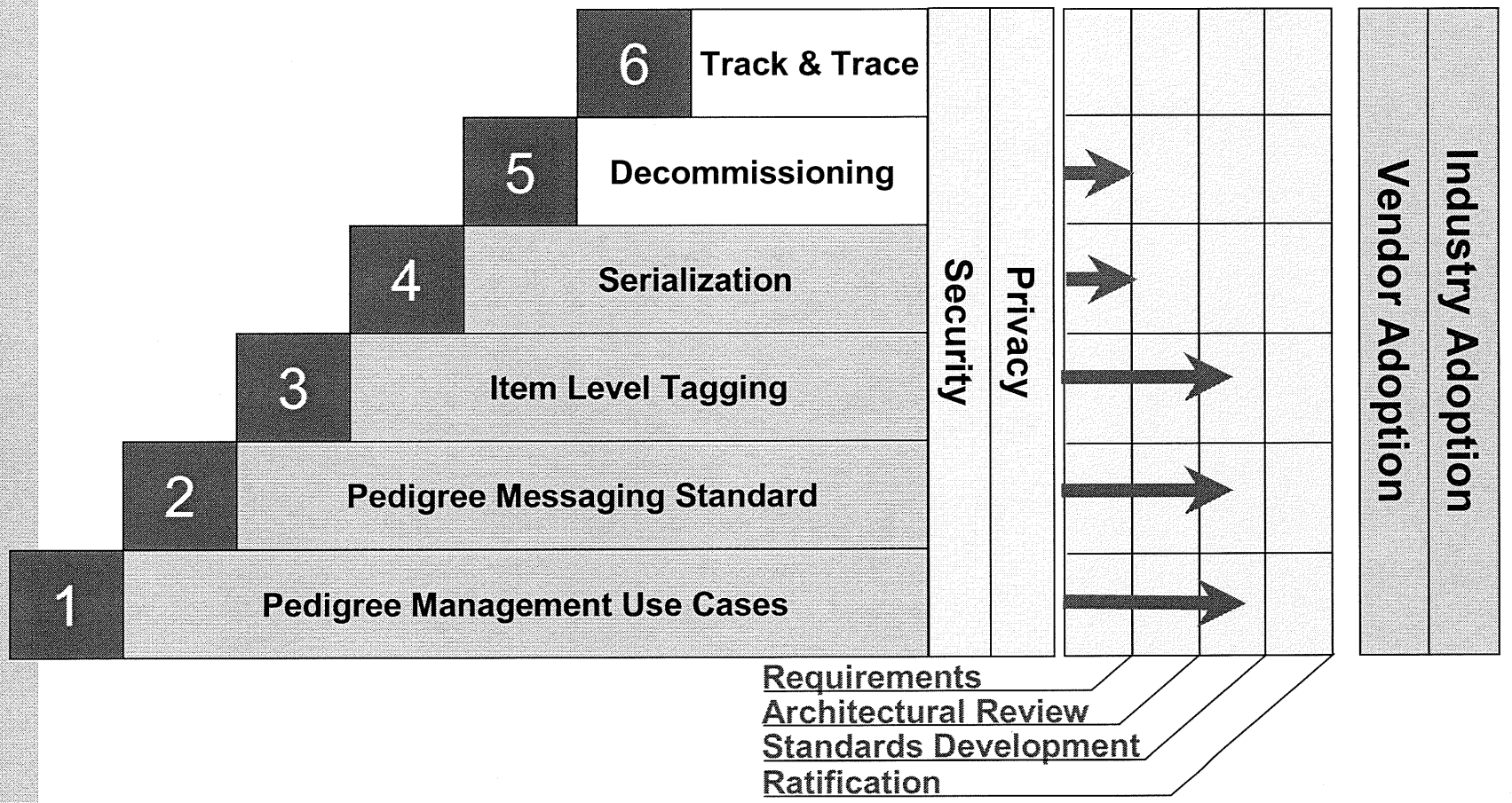
Technology Challenges:

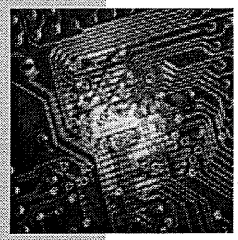
- **Serialization**
- **Tag Frequency**
- **Performance**
- **Package Size**
- **Physical Characteristics**
- **Event Vocabulary**



E-Pedigree Standards

State of the Standards





E-Pedigree Standards

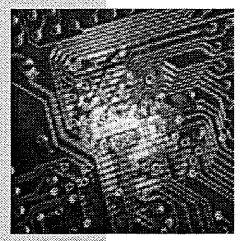
Key Objectives and Process Requirements

Objectives:

- Provides **universal interchange format** to express pedigree requirements of varied state regulations as drug products flow from one state to another
- Enable trading partners to send and receive pedigrees in a **secure and interoperable** manner that leverages existing B2B technologies and processes

Process Requirements:

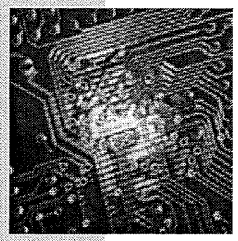
- Each party engaged in the wholesale distribution of prescription drugs must **provide a pedigree** to the recipient for sales, returns, and transfers of prescription drugs
- Pedigrees must contain a **certification** (via signature) by the sender that the information is true and accurate
- Pedigrees must be **authenticated** by the recipient prior to receipt of drugs
- Recipient must add **receipt and authentication signature** to pedigree
- A pedigree received by or provided by an organization is a **subject to recordkeeping requirements** for record retention and record availability



E-Pedigree Standards

E-Pedigree Interchange Requirements

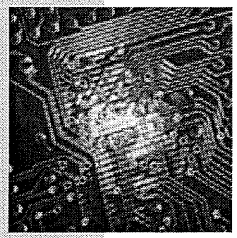
- Common format that meets PDMA and state needs
  - **Supports all required data elements for PDMA and states**
  - **Extensible format supports future state requirements**
- Supports regulatory and business requirements
  - **Serialized items (Could potentially support Non-serialized items with additional study)**
  - **Repackaged products**
  - **Sales, transfer, and return transactions**
  - **Creating electronic pedigree from paper pedigree**
  - **Digital signatures and electronic authentication**
- Enables interoperability among trading partners
  - **Representation of pedigrees in a common portable format**
  - **Exchange using existing business data transfer mechanisms**
- Supports Standard Security Protocols
  - **Public Key Infrastructure (PKI)**



Next Steps

Beyond Standards Ratification

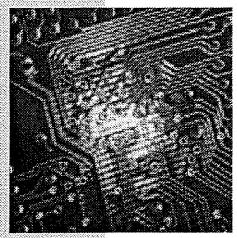
- Capital Planning
- Process Reengineering
- Systems Integration
- Infrastructure Build-Out
- Scale-Up



E-Pedigree Standards

Pedigree Data Elements

- **Product Information**
  - Drug name
  - Manufacturer
  - Product NDC, dosage form, strength, container size
- **Item Information**
  - Lot number and expiration date
  - Quantity of units by lot
  - Product serial number (if serialized)
- **Transaction Information**
  - Transaction identifier (e.g., PO, Invoice) and date
  - Transaction type (e.g., sale, transfer, return)
  - Date received
- **Trading Partner Information**
  - Business name, address, and license of seller
  - Alternate ship-from location of seller
  - Seller contact information for authentication
  - Business name, address, and license of recipient
  - Alternate ship-to location of recipient
- **Signatures/certifications**
  - Digital signature of seller
  - Digital signature of recipient



Thank You!!

ATTACHMENT B

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

D R A F T

PRESCIPTION DRUG PEDIGREE

March 2006

Introduction
In 2004, the California State Board of Pharmacy sponsored legislation that made comprehensive changes to the wholesale distribution system to protect against counterfeit drugs.

The Center for Medicines in the Public Interest projects that the number of counterfeit drug sales will reach $75 billion by 2010, a 92 per cent increase from 2005. The board's statutes require the development of a "pedigree" that tracks each prescription drug through the distribution system beginning January 1, 2007. The statutes also require licensure of out-of-state wholesalers, the posting of a $100,000 surety bond (or equivalent security), and authorize the board to embargo drugs when the board suspects drugs are adulterated or counterfeit.

The following are questions that the Board of Pharmacy has received regarding the implementation of the pedigree requirement and proposed answers.

QUESTIONS AND ANSWERS

General Questions

Q1 What is a pedigree?

A pedigree is an electronic record containing information regarding each transaction resulting in a change of ownership of a prescription drug (dangerous drug) from the sale by the manufacturer through each acquisition and sale of the drug until the final sale to a pharmacy or prescriber who will furnish, administer or dispense the prescription drug to a patient. (B & P § 4034(a))

Q1.1 Is the pharmacy required to track the pedigree to the patient?

The pedigree ends with the pharmacy or other entity (person) that dispenses, administers or furnishes the prescription drug. Thus, it is not required that the pedigree record the transaction between the pharmacy and the patient.

Q2 What are the requirements for a pedigree in California?

Source of the Prescription Drugs
At each stage or link in the distribution chain down to the end user, a pedigree must contain information on each source/prior owner of the prescription drug. Information regarding the source will include the manufacturer, wholesaler and in some instances, the pharmacy from which the prescription drug was acquired and/or through whose ownership the prescription drug passed. It is any entity that is selling, trading or transferring the prescription drug. The pedigree must include each source's name and principal address and California license number if available.

Prescription Drugs and Transaction Information
The pedigree shall include the name of the prescription drug, its quantity, its dosage form and strength, the date of each transaction in its distribution to that point, the sales invoice number(s) associated with each such transaction, the container size(s) for each transaction, the number of containers for each transaction, the expiration dates and the lot number(s).

Prescription Drug Ownership Information
The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the prescription drug, and the prescription drug shipping information, including the name and address, of each person certifying to delivery and receipt of the prescription drug.

A California license is required to authorize an entity to possess, acquire, sell or transfer prescription drugs in California.

Certification of Transaction Authenticity
A certification under penalty of perjury from a responsible party of the source of the prescription drug that the information contained in the pedigree is true and accurate. (B & P § 4034(b))

Q2.1 Does the law require that the NDC number be included in the pedigree?

Section 4034 does not require the NDC number as part of the pedigree, nor does it prohibit inclusion thereof along with the required pedigree data.

Q2.2 Please clarify "California license number."

Section 4034, subparts (b)(1) and (b)(3), specify that the pedigree shall include, for the source of the prescription drug and each owner thereof, a California license number if available.

Q2.3 Can the person who authenticates receipt of the prescription drug be an agent of the manufacturer, wholesaler or pharmacy?

The person certifying the authenticity of the pedigree must be a "responsible party," i.e., an individual authorized to act on behalf of the entity selling or receiving the prescription drug, and whose attestation/signature may bind the entity.

Q3 When does the pedigree requirement become effective? (B & P § 4034(e))

The pedigree requirement becomes effective January 1, 2007.

Q4 What types of drugs require a pedigree?

All prescription drugs (dangerous drugs), including controlled substances, require a pedigree.

Q5 Does prescription drugs include prescription drugs for animals?

The definition of "dangerous drug" means any drug unsafe for self-use in humans or animals and includes any drug bearing the legend: "Caution: federal law prohibits the dispensing without prescription, "Rx only," or words of similar import. (B & P § 4022)

Q6 When is a pedigree required?

Beginning January 1, 2007, a California licensed wholesaler or pharmacy may not acquire a prescription drug (dangerous drug) without a pedigree. A California licensed wholesaler or pharmacy also may not sell, trade or transfer a prescription drug at wholesale without providing a pedigree.

Q7 Who creates or starts a pedigree?

The pedigree must reflect every change of ownership of the prescription drug beginning with sale by a manufacturer. The manufacturer initiates the pedigree.

Q8 When does the required information need to be recorded on the pedigree? When there is movement of the prescription drug or a change of ownership of the prescription drug?

Any change of ownership of the prescription drug requires documentation of the transaction information on the pedigree.

Q8.1 What does "change of ownership" mean?

Section 4034 defines the required pedigree to be an electronic record containing, among other things, information regarding each transaction resulting in a change of ownership of a given prescription drug. "Change of ownership" is not given to specific meaning by the statute that would depart from the generally understood meaning thereof, and shall be determined on a case-by-case basis according to that generally understood meaning. Change of ownership may or may

not always coincide with a change in possession. Possession is a strong indication of ownership, so the presumption is that change in possession is an indicator of change of ownership. However, this is not a conclusive presumption, and it may be appropriately rebutted.

Q 9 When are additional entries made on the pedigree?

Each time that the ownership of the prescription drug changes, the required transaction information must be recorded on the pedigree. The responsible party of the source who is selling, trading or transferring the prescription drug must certify that the pedigree is true and accurate and thereby authenticate the transaction information.

Q10 What types of "change of ownership" transactions require documentation on the pedigree?

While not a comprehensive list, the following transactions may require documentation on the pedigree if a change of ownership has occurred:

- Any sale, trade, or transfer of prescription drugs between a manufacturer and wholesaler
- Any wholesale sale to a pharmacy, other wholesaler, clinic or prescriber (This would include "wholesale brokering" where the wholesaler doesn't take possession of the prescription drug but makes arrangements for the delivery of the prescription drug and processes the paperwork.)
- Drop ship deliveries for a manufacturer, wholesaler or pharmacy
- Consignment transactions
- Third party logistics transactions
- Pharmacy sales to another pharmacy as authorized by B&P § 4126.5
- Pharmacy returns to the wholesaler or manufacturer from whom the prescription drugs were originally purchased
- Pharmacy sales to a prescriber or other licensed entities authorized to receive drugs
- Pharmacy or wholesale transfers to a reverse distributor.

In this sample question and answer (and others following), the board has provided examples of transactions that do or may constitute a "change of ownership." This is neither a comprehensive list nor does the inclusion of a transaction type on the board's list mean that in every case such a transaction creates or constitutes a "change of ownership." Except where the board is aware that certain transfers of possession do not constitute changes in ownership, the board begins with the presumption that change in possession indicates a change in ownership. But that is not always the case and that presumption can be rebutted. What is significant is not whether a transaction fits a type identified by the board as presumably constituting a "change of ownership," but whether an actual change of ownership has occurred.

While a particular transfer/transaction may not need to be recorded on the pedigree, the record-keeping requirement for acquisitions and dispositions is separate from and additional to the

pedigree requirement. The transferring entity must still provide the pedigree (recording the transactions to that point) to the transferee, and the transferee (and/or the first entity) must still provide that pedigree to any subsequent transferee.

Q10.1 What is a third party logistics provider and why is it included? How is a third party logistics provider different from a common carrier?

The board's working definition of a third party logistics provider is a provider that stores the prescription drugs and then delivers the drugs at some time in the future at the direction of the manufacturer. A common carrier takes possession of prescription drugs for however long it takes to deliver the prescription drugs to their destination (e.g. UPS ground, or next day air, yellow freight, or federal express.) A common carrier is not licensed in California; however, a third party logistic provider is licensed as a wholesaler because they store prescription drugs. In addition, a third party logistics provider could commonly receive 10 cases of a particular prescription drug and may deliver either a case, or an individual manufacturer's container to a pharmacy. A common carrier does not manipulate the product in any way; they just deliver it.

Q11 What transactions are not required to be recorded on the pedigree?

The following transactions do not require a pedigree entry:

- Any transfer of a prescription drug between individuals or entities that does not constitute or result in a change of ownership of the prescription drug.
- Any transaction of dangerous devices
- Any transaction of non-prescription drugs (over-the-counter drugs)
- Prescription drugs provided as a part of a manufacturer's patient assistance program, i.e., where the prescriber requests the prescription drugs from a drug manufacturer and the prescription drugs are delivered to the prescriber by the manufacturer, to be dispensed to the prescriber's patient
- Complimentary prescription drug samples ordered by a prescriber from a manufacturer and delivered to the prescriber for future dispensing to a patient at no charge

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q11.1 Do prescription drug samples provided to a wholesaler from a manufacturer require a pedigree?

A drug sample is a prescription drug. A wholesaler may not acquire a drug sample (prescription drug) without receiving a pedigree. There is no exemption for acquisitions by wholesalers that

are complimentary or otherwise not purchases, and this transaction would be a change of ownership requiring documentation on the pedigree.

This is different from direct acquisition by a prescriber from a manufacturer where no pedigree is required by statute.

Q12 What other types of transactions are not considered a change of ownership and therefore would not require documentation on the pedigree?

Prescription drugs distributed or transferred between, within or among a licensed health care services plan, a hospital organization, and one or more physicians organizations having an exclusive contractual relationships to provide health care services, are not deemed to have changed ownership. (B&P § 4034(c))

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q12.1 Who is responsible for the record-keeping requirement for the pedigree if the prescription drug is transferred to another entity (person) and the transaction does not constitute a change of ownership of the prescription drug?

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q 13 When does the pedigree need to be verified and authenticated?

The pedigree needs to be verified and authenticated when any recipient in the chain of distribution (e.g., wholesaler, pharmacy, prescriber) receives the prescription drug and the pedigree.

Manufacturer/Wholesaler Questions

Q1 Where in the supply chain does the pedigree start?

The pedigree starts at the manufacturer.

Q2 Does a wholesaler or pharmacy have to use the pedigree it receives or can it create a different pedigree?

A wholesaler or pharmacy must use the pedigree in the form that it is received. The wholesaler or pharmacy cannot create a different pedigree.

Q3 If a pharmacy returns prescription drugs to the manufacturer or wholesaler from which the prescription drugs were purchased, does this transaction need to be recorded on the pedigree? If the prescription drugs are sold to a pharmacy and the pharmacy returns the prescription drugs within 7 days, is that transaction exempt from documentation on the pedigree?

Any returns to a manufacturer or wholesaler, or any other change of ownership, requires documentation on the pedigree. There is no exemption from the pedigree for prescription drugs that are returned within 7 days. All prescription drug returns require a pedigree. Returns to the manufacturer or wholesaler must be in accordance with B & P § 4126.5.

Q4 Do wholesalers who only broker prescription drugs have to receive a pedigree when making arrangements for shipment of prescription drugs, and do wholesalers in such transaction have to provide a pedigree when the prescription drugs are sold?

Yes, a wholesaler who brokers prescription drugs must receive a pedigree and provide a pedigree to the individual or entity receiving the prescription drugs.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q5 Would a third party logistics provider that receives a prescription drug from the manufacturer and ships the prescription drug to the wholesaler be considered a manufacturer and therefore be required to start the pedigree?

The manufacturer is required to start the pedigree. If the manufacturer ships the prescription drug to a third party logistics provider, that third party provider must be licensed as a wholesaler and

the transaction must be recorded on the pedigree that started with the manufacturer if there is a change of ownership of the prescription drug.

Each licensed wholesaler that receives the prescription drug and ships the prescription drug would be required to be on the pedigree if the prescription drug changes ownership.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q6 Do wholesalers who only store and ship consigned prescription drugs have to receive a pedigree when they receive the prescription drugs? Would a pedigree be required when the prescription drugs are distributed?

Yes, wholesalers who receive consigned prescription drugs and then deliver the prescriptions drugs upon request of the consignor must receive a pedigree upon receipt of the prescription drugs and must issue a pedigree to the individual or entity to whom or which the prescription drugs are delivered.

Another example is where a manufacturer or wholesaler owns the prescription drugs, but the prescription drugs reside at another licensed wholesale facility and are billed by the original manufacturer or wholesaler at the time of sale, while they are delivered by the wholesaler storing the prescription drugs. A pedigree would be required that documents each change of ownership, including the transaction from the manufacturer to the wholesaler where the prescription drugs reside, as well as the subsequent sale and delivery.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q7 Do manufacturers or wholesalers who have another wholesaler drop ship a prescription drug have to receive a pedigree when arranging for the drop shipment and issue a pedigree when distributing the prescription drug?

Yes, a drop shipment requires a pedigree entry if there is a change of ownership of the prescription drug.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q8 What does a wholesaler do with prescription drugs in their possession on January 1, 2007 that do not have a pedigree?

A licensed wholesaler may create a pedigree with the wholesaler listed as the original creator of the pedigree only for those prescription drugs in its possession on January 1, 2007. The wholesaler (creating the pedigree) should retain purchase invoices or other documentation confirming the date of purchase and receipt of any prescription drugs in its possession before January 1, 2007 for which a pedigree is created until all prescription drug stock held on January 1, 2007 is sold, traded or transferred or 3 years whichever is longer.

Q9 Is the shipping address required on the pedigree? If so, does that mean the corporate office or the actual location from where the prescription drug was shipped?

The shipping address is the address of the location **from** which the prescription drug was actually shipped or the actual address **to** which the prescription drug was shipped and delivered.

Q10 What is a sales invoice number?

The board's operational definition is that a sales invoice number is a unique number created by each manufacturer or wholesaler in the chain of distribution and used by each manufacturer or wholesaler to identify the invoice that documents the sale transaction of a prescription drug. The sale transaction would include any purchase, trade or transfer of a prescription drug resulting in a change of ownership. The statute specifies sales invoice number.

Q11 The pedigree requires the "source" of the drug. What is the source?

The source is the entity or entities selling, trading or transferring the prescription drug. Depending on the transaction, the "entity" may be the manufacturer, wholesaler, pharmacy, and/or prescriber.

Q12 What happens to a pedigree when a licensed repackager repackages a prescription drug?

In California, an entity that repackages prescription drugs must be licensed as a manufacturer. When a prescription drug is repackaged, it will typically acquire a new NDC number, lot number

and perhaps expiration date. The repackager must receive a pedigree with the prescription drug and the new pedigree information (new NDC number, etc.) must be documented on the original pedigree and continue with the newly repackaged prescription drug.

Q12.1 By affixing a new NDC number to a repackaged prescription drug, is a repackager exempt from the requirement of providing a pedigree?

No, when the pedigree requirement becomes effective, a repackager will be required to provide a pedigree back to the original manufacturer.

Q13 Is a pedigree required for an intra-company transfer between manufacturer and wholesaler?

A pedigree is required to contain information regarding each transaction resulting in a change of ownership of a given prescription drug.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q14 What are the pedigree requirements for prescription drugs that are shipped into California?

Prescription drugs that are shipped into California are required to have documentation of each transaction from the manufacturer, to acquisition and sale by a wholesaler until final sale to the pharmacy. Only those transactions that result in a change of ownership of the prescription drug are required to be documented on the pedigree.

Q15 Is it possible for a wholesaler or pharmacy to update its inventory before a pedigree is authenticated?

If a wholesaler or pharmacy receives delivery of a prescription drug but has not authenticated the pedigree, the prescription drugs may be stored under secure conditions for a brief period of time, separated from the regular inventory, until the pedigree may be verified. Any such unverified prescription drugs may not be stored with regular inventory or be available for sale until the pedigree is authenticated.

Q16 Is it acceptable to list multiple prescription drugs, which were all purchased from the same manufacturer at different times on a single pedigree as long as the date of purchase and associated invoice number(s) are listed with each drug?

It is expected that the required pedigree elements will be kept at all times in a readily retrievable form at the facility or pharmacy from which, by which, or to which prescription drugs are distributed. The statutes do not specify how the pedigree data is stored.

Q17 Would it be acceptable to post pedigree information on a secure site for customers to access? There is concern about the amount of paper recipients of pedigrees at the pharmacy and wholesalers would need to manage, as well as the funds they would have to invest to secure their own pedigree solution. With this approach, all they would need to invest in would be an Internet access to their supplier's existing infrastructure?

It is expected that the required pedigree elements will be kept at all times in a readily retrievable form at the facility or pharmacy for which, by which, or to which prescription drugs are distributed. The statutes do not specify how the pedigree data is stored.

Pharmacy Questions

Q1 Are pharmacies required to obtain a pedigree when buying prescription drugs?

Effective January 1, 2007, a pharmacy may not acquire any prescription drugs (dangerous drugs) without obtaining a certified pedigree at the time the drugs are acquired.

Q2 Are pharmacies ever required to provide a pedigree?

A pharmacy is required to provide a pedigree as part of any transaction resulting in a change of ownership of a given prescription drug, including but not limited to when the pharmacy returns a prescription drug to the wholesaler or manufacturer from which the prescription drug was obtained, when the pharmacy wholesales the prescription drug to another pharmacy to alleviate a temporary shortage, when the pharmacy transfers the prescription drug to a health care provider authorized to purchase prescription drugs, or when the pharmacy sends a prescription drug to a reverse distributor. The pharmacy is required to provide a pedigree at the time of any sale, trade or transfer of a prescription drug resulting in a change of ownership.

A pedigree is not required if the transaction does not result in the change in ownership of the prescription drug. However, the transaction must be one of the transactions authorized by B& P § 4126.5.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be

recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q3 To whom can a pharmacy furnish prescription drugs? (B& P § 4126.5)

- A wholesaler owned or under common control by the wholesaler from which the prescription drug was acquired.
- The pharmaceutical manufacturer from which the prescription drug was acquired.
- A licensed wholesaler acting as a reverse distributor.
- Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. Only a quantity sufficient to alleviate the temporary shortage may be furnished.
- A patient or another pharmacy pursuant to a prescription or as otherwise authorized by law.
- A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.
- To another pharmacy under common control.

Q4 Is a pedigree required for an intra-company transfer of drugs between pharmacies?

A pedigree is required to contain information regarding each transaction resulting in the change of ownership of a given prescription drug. Any transfer from or by a pharmacy must be in compliance with B& P § 4126.5.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q5 What does under "common control" mean?

Common control means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

Q6 Is a pedigree required when a prescription drug is transferred between pharmacies under common control?

A pedigree is required to contain information regarding each transaction resulting in the change of ownership of a given prescription drug. Any transfer from or by a pharmacy must be in compliance with B& P § 4126.5.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

Q7 What does a pharmacy do with prescription drugs in their possession on January 1, 2007 that do not have a pedigree?

A pharmacy must be able to document those prescription drugs that it has in its possession on January 1, 2007. The documentation should include lot numbers and expiration dates. A pharmacy would be required to create a pedigree for those prescription drugs that are transferred from or by the pharmacy in compliance with B& P § 4126.5.

Prescriber Questions

Q1 Are prescribers required to receive a pedigree when they purchase prescription drugs?

The wholesaler or pharmacy is required to provide a pedigree for any change of ownership including to a prescriber.

Q2 Are prescribers required to provide a pedigree?

A wholesaler or pharmacy is required to receive a pedigree for any prescription drug that is acquired including from prescribers.

General Technology Questions

Q1 What type of technology is required?

The only requirement is that the pedigree be electronic; no specific technology is required.

California wholesalers, pharmacies and other healthcare providers that sell, trade, transfer or receive prescription drugs must ensure the authenticity, integrity, and non-repudiation of the electronic pedigree.

The California Board of Pharmacy does not provide specific directions or technological requirements on how to ensure the authenticity, integrity and non-repudiation of the electronic pedigree. It is the responsibility of the involved parties to meet these requirements in whatever way best suits the circumstances in question.

Q2 What does "in electronic form" mean?

The statute does not define "in electronic form" or the technology required. With input from the stakeholders, if necessary that can be accomplished by regulation, or by subsequent statute.

Q3 Can the wholesaler and pharmacy maintain the pedigree record electronically?

California law requires that records of the manufacture, sale, acquisition and distribution of prescription drugs be available on the licensed premises for three years from the date of making (B&P § 4081, 4105, and 4333.) The pedigree record may be kept electronically so long as a hard copy and an electronic copy can during that period always be produced (B&P § 4105.)

Q4 Can a manufacturer or wholesaler provide a database containing more information than required by California as long as the electronic pedigree requirements for California are part of the data?

As long as the required pedigree data is provided and is readily retrievable upon inspection or otherwise, additional data may also be collected.

Q5 Is the lot number of a drug required on the pedigree? Can multiple lot numbers be on the pedigree document?

The lot number is required. Multiple lot numbers can be on the pedigree as long as the wholesaler or pharmacy can readily retrieve the lot number upon request without having to do a manual search for the required lot number.

Q6 Is Radio Frequency Identification (RFID) technology required?

No, RFID is not required.

Q7 If a California wholesaler or pharmacy ships out of state, how will the out of state entity receive the pedigree if they do not have the appropriate software?

If another state requires a pedigree, then the California wholesaler or pharmacy must comply with the receiving state's pedigree requirement as well as California's requirements. If the state does not require a pedigree, the California wholesaler or pharmacy would still be required to document the transaction on the electronic pedigree and provide it to the receiving entity. If the receiving entity does not have the software to read the pedigree, it would be advisable for the California business selling the prescription drug to provide a printed hard copy of the electronic

pedigree. In order to be shipped back into or received in California, the prescription drug would have to have a complete electronic pedigree.

Q8 Is there a clearinghouse for the transaction data for electronic pedigrees?

At the current time, there is no clearinghouse for pedigree data.

Q9 Is there a hotline to verify pedigree data provided by the wholesaler?

At the current time there is no hotline to verify the authenticity of data provided in a pedigree.

Q10 To read and accept an electronic pedigree, is a wholesaler required to provide software to its customer pharmacies or will pharmacies have to procure the needed software?

There is no requirement for a manufacturer or wholesaler to provide the necessary software to read an electronic pedigree.

Q11 Will everyone need a scanner or other hardware to comply with the pedigree requirement?

The type of technology used will determine the hardware and software needs of a business. There is no requirement for a particular type of technology.

Regulatory Questions

Q1 Is any additional legislation regarding the pedigree being considered in California?

No legislation is pending or proposed at this time.

Q2 California law provides for an extension to implement the pedigree requirement until January 1, 2008, if the Board of Pharmacy determines that manufacturers or wholesalers require additional time to implement electronic technologies to track prescription drugs within California. How would the board grant this extension?

The Board of Pharmacy would have to grant the request at a public meeting. A written request to extend the implementation date for the pedigree can be sent to the attention of the Executive Officer Patricia Harris, at 1625 N. Market Blvd. Ste N219, Sacramento, CA 95834.

Q3 Does a manufacturer have to be licensed in California to sell prescription drugs in California?

No, if the manufacturer only sells the prescription drugs it actually manufactures, and the prescription drugs are distributed solely from the premises of the licensed manufacturer.

Q4 How will the Board of Pharmacy be enforcing the pedigree requirement for pharmacies and wholesalers?

Compliance will be confirmed through board inspections and complaint investigations.

Q5 How will the board's inspector know if a pedigree has been provided to a pharmacy or wholesaler for a specific drug?

As a part of an inspection or investigation of a California wholesaler or pharmacy, the inspector would verify the receipt and verification of pedigree documents and the procedure for providing a pedigree when drugs are sold, traded or transferred.

Q6 If an inspector asks for the pedigree of a specific prescription drug, does the pharmacy need to provide one single pedigree, or it is acceptable for the pharmacy to state that it is one of these 10 pedigrees?

The pedigree must be provided upon request for the exact prescription drug that is requested by the inspector. It may be contained in a document with 10 other products, but the pharmacy would have to locate and provide the exact pedigree to the inspector.

Strategies to avoid Counterfeit, Misbranded or Adulterated Drugs

1. Know your supplier. Deal only with trustworthy, reputable wholesalers. Just because a wholesaler has a license does not necessarily mean it is trustworthy.
2. Be careful of the "good deal." If something appears to be too good to be true, be careful, especially with a new supplier. Due diligence is needed to check on suppliers.
3. Be careful of fax and email deals you receive.
4. Look for signs of removed labels – look for a tacky adhesive residue on or near the label.
5. Look for discolored labels. The solvent used to remove original print may discolor the label.
6. Look for slight differences in bottle or container size
7. Listen to patients – many drug counterfeits are caught by patients

8. Look for changes in lab/test values; a worsening in the patient may be due to an ineffective and/or counterfeit medication.
9. Ask the patient if they are using drugs purchased from foreign sources
10. If you suspect something is wrong contact the FDA at hhtp://www.fda/gove/medwatch or 1-800-FDA-1088 , contact the manufacturer, contact the State Board of Pharmacy

Related Pharmacy Law

Effective January 1, 2007

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source.

(2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(d) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(e) This section shall become operative on January 1, 2007.

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.
(b) Notwithstanding any other provision of law, a violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities may subject the persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.
(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.
(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.
(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

Effective January 1, 2007
4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.
(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.
(c) A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.
(d) A wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.
(e) This section shall become operative on January 1, 2007.

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Section 4163 until January 1, 2008, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

4163.6. If the Legislature determines that it is not yet economically and technically feasible for pharmacies to implement electronic technologies to track the distribution of dangerous drugs within the state, the Legislature may extend the date for compliance with the requirement for a pedigree for pharmacies set forth in Section 4163 until January 1, 2009.

ATTACHMENT C

CALIFORNIA RETAILERS ASSOCIATION
980 NINTH STREET, SUITE 2100 · SACRAMENTO, CA 95814
(916) 443-1975 · FAX (916) 441-4218

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES
413 North Lee Street, P.O. Box 1417-D49 • Alexandria, Virginia 22313-1480
(703) 549-3001 Fax (703) 836-4869

April 6, 2006

Ms. Patricia Harris
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

RE: Implementation of the Electronic Pedigree Requirement for Prescription Drugs Effective January 1, 2007

Dear Ms. Harris:

The National Association of Chain Drug Stores (NACDS) and the California Retailers Association (CRA) are writing on behalf of our members to request a delay in the implementation date for the electronic pedigree requirements and address the Board of Pharmacy's request for a timeline regarding implementation of electronic pedigree from industry stakeholders. Collectively, our organizations represent the leading retail chain pharmacies and suppliers. Our members range in size from four pharmacies to over 5,000 pharmacies.

It is critical to the chain pharmacy industry that consumers have confidence in their pharmacies, pharmacists and the prescription drugs they dispense. Our members believe that it takes a concerted effort of all parties in the prescription drug supply chain to make our drug distribution system among the safest and most secure in the world. We applaud the efforts of the Board of Pharmacy in working toward systems that will further tighten the security of the drug supply chain in California. Our members support the efforts of the Board of Pharmacy to find solutions that are cost-effective and realistic, and we look forward to continuing to develop workable solutions.

Regarding the implementation of e-pedigree, the members of NACDS and CRA find themselves in a frustrating position. Pharmacies are the last link in the drug supply chain. Thus, to comply with the electronic pedigree requirement, pharmacies could be forced to support a variety of e-pedigree software packages and solutions, depending upon the approach that is chosen by manufacturers and distributors.

Until the manufacturers and wholesalers decide how they would create and pass an electronic pedigree, it is impossible for the community pharmacy industry to provide a timeline. The community pharmacy industry is proceeding in good faith, attempting to participate in all relevant discussions about how electronic pedigrees can be implemented in a timely and efficient manner, and encouraging our partners in the drug supply chain to do the same.

In the spirit of good faith, our members are taking steps to advance the progress of electronic pedigree implementation. Our members were the industry stakeholders to formally request in December 2005 that the Board of Pharmacy establish an e-Pedigree workgroup to examine the issues surrounding the implementation of California's e-pedigree requirement. NACDS and CRA are in the process of jointly sending letters to each manufacturer and every wholesaler with whom our member companies contract conveying our sense of urgency that they participate in EPCglobal's efforts to establish pedigree standards and participate in the Board's e-pedigree workgroup meetings. Additionally, our members will be participating in the newly formed coalition of community pharmacies, manufacturers, and distributors to work on California electronic pedigree implementation plans and milestones. HDMA and its member wholesalers are organizing this coalition. We anticipate that the McKesson Corporation will host the first coalition meeting on April 25, 2006 in San Francisco.

Many of our members have become actively involved with EPCglobal, the nonprofit, standard-setting body for RFID. One of the work products that EPCglobal is working on is the establishment of an RFID-enabled electronic pedigree. An RFID-enabled pedigree is different from an electronic pedigree. The RFID enabled e-pedigree is a serialized pedigree that enables each bottle to have a unique number. We are working diligently within EPCglobal to research and potentially develop an RFID enabled electronic pedigree system. To help facilitate a uniform pedigree, NACDS and our members participate in the Unified Drug Pedigree Coalition with a number of other industry stakeholders including NABP, and the FDA. While there is work underway, we need more time to ensure that we can create an electronic pedigree that is interoperable among technology vendors and the various states and other stakeholders.

In the absence of a standardized electronic pedigree system, community pharmacy cannot provide an accurate timeline for when we will be capable of complying with the current legislative requirements. We do not think it reasonable that community pharmacy should bear the cost of supporting multiple software solutions. Therefore, we would encourage the Board of Pharmacy to require that all software vendors that offer a solution for the California e-pedigree requirement certify that their software is interoperable. Once we have interoperable software, community pharmacies can begin to pilot and validate these systems. We would also want to make sure that the software can work in real-time so not to affect our productivity in our distribution centers or in our pharmacies. This process, from the time we have interoperable software through the phases of testing, validation and deployment across all pharmacies in California, could take as long as two years.

NACDS and CRA must make it perfectly clear: Our members feel strongly that any requirement for electronic pedigrees before national standards are established is ill-advised. With electronic pedigree standards still being developed, pharmacies will have to use any and all systems the manufacturers and wholesalers decide to use. In a competitive market, it is therefore foreseeable that this could result in both chain and independent pharmacies being forced to invest in dozens of electronic pedigree systems, all of which could potentially be obsolete in a very short time period.

While not discounting the possibilities that some of today's emerging technologies, such as RFID, may provide future improvements to the drug supply chain integrity, these technologies remain unproven and significant time will be required to fully develop and understand their capabilities. In the meantime, there are practical and immediate initiatives that have been undertaken to improve the integrity of the drug supply chain. Some of these initiatives have been driven by industry and some through legislation.

Community Pharmacy Initiatives

Community pharmacy has taken a leadership role in adopting practical and immediate steps to further ensure the integrity of the products they dispense. Many pharmacies have made changes in their purchasing practices such as requiring their wholesale distributors to purchase their products directly from manufacturers. Additionally, community pharmacy supported California's efforts to strengthen wholesale licensing requirements. These stricter requirements have removed the unscrupulous wholesale distributors from operating within the legitimate drug supply chain.

Wholesale Distributor Initiatives

The wholesale distribution industry has also taken dramatic steps to further ensure the integrity of the products they distribute. Many wholesale distributors, including the nation's three largest wholesale distributors, have indicated they would no longer trade with secondary wholesalers. This practice was historically a potential entry point for counterfeit products and contributed heavily toward drug diversion. The elimination of this practice creates a direct flow of product from the manufacturer to the wholesale distributor to the pharmacy, and finally to the patient.

Additionally, the wholesale industry has migrated towards a Fee-For-Service / Inventory Management Agreement relationship with manufacturers. This move has eliminated the speculative purchasing on the part of the wholesale distributors. Historically, this activity was an integral piece of the wholesale distributors' business model; it allowed them to capitalize on the incremental revenue that could be gained in advance of manufacturers' price increases. With the advent of these agreements, new relationships between wholesale distributors and manufacturers have been developed that have resulted in less excess inventory in the drug supply chain. Less excess inventory in the drug supply chain has helped to eliminate questionable entities from participating in the legitimate drug supply chain.

Pharmaceutical Manufacturer Initiatives

Pharmaceutical manufacturers have become more restrictive in their selling practices, ensuring that they sell their products only to legitimate operators within the drug supply chain. Manufacturers have also embraced the Fee-For-Service and Inventory Management Agreements with wholesale distributors as it allows them tighter control of the quantity of product in the drug supply chain at any point in time. Additionally, manufacturers are increasingly using overt counterfeit measures such as color shifting ink to make their products more difficult to counterfeit.

State Initiatives

As you know, many states have adopted laws and regulations with more stringent requirements for licensure of wholesale drug distributors and drug distribution records intended to minimize the risk of counterfeit drugs appearing in their state.

While there appears to be uniformity in the states efforts to strengthen wholesale licensing requirements, no two state pedigree requirements are exactly the same. For instance, beginning July 1, 2006, the State of Florida will be requiring paper or electronic pedigrees documenting both the chain of custody and change in ownership for all wholesale distributions, the State of Indiana has adopted the "normal distribution channel" approach which requires pedigrees for only those products that are distributed outside the defined normal distribution channel, and the State of California on January 1, 2007, will require an electronic pedigree beginning with the manufacturer that documents only the ownership changes of a prescription medication. These differences in pedigree requirements present a significant challenge for community pharmacies.

Our member companies enthusiastically support efforts to find solutions to drug counterfeiting that are realistic and cost-effective, and we thank the Board of Pharmacy for the opportunity to continue to develop workable solutions. As the drug supply industry attempts to implement solutions, we believe that these practical and immediate industry initiatives combined with state-level initiatives represent viable solutions in the interim.

The Board's Ultimate Goal Should Be the Adoption of RFID Technology

NACDS and CRA support the establishment of electronic pedigrees and we look forward to the promise of RFID technology. RFID technology promises to eventually eliminate the need for paper pedigrees. Unfortunately, RFID technology solutions are not yet ready for full implementation across the drug supply chain. We believe that any requirement for pedigrees before RFID track and trace technology is widely available and nationally standardized will cause stakeholders to incur incalculable costs resulting from a variety of temporary alternatives to RFID that ultimately will not succeed. This will cause them to invest time, effort and capital into other less beneficial e-pedigree technologies, thus taking resources away from implementing nationally standardized and operational RFID technology. Consequently, RFID technology implementation would be further delayed.

Request for Delay of Electronic Pedigree Implementation

We must unfortunately ask that the Board of Pharmacy delay implementation of California's electronic pedigree requirement. Ideally, implementation of the electronic pedigree requirement will not go into effect until the necessary stakeholders in the drug supply chain are given the opportunity to adopt RFID technology. However, if the Board of Pharmacy decides that more immediate action is necessary, then our members would like to recommend to the Board of Pharmacy solutions that are more reasonable than a mandate of pedigree requirements across the drug supply chain starting January 1, 2007.

Recommended Solutions

1. "Normal Distribution Channel" Addresses Counterfeiting Concerns

NACDS and CRA support a concept that has been adopted by many states including Arizona, Indiana, Oklahoma, and Texas, as well as embraced by the National Association of Boards of Pharmacy (NABP) and other stakeholders in the prescription drug supply chain, namely, the concept of the "normal distribution channel." Normal Distribution Channel has been defined as the: "chain of custody during distribution of prescription medication that goes from [1] the manufacturer to a wholesale distributor to a pharmacy or [2] the manufacturer to a wholesale distributor to a chain pharmacy distribution center to their intra-company pharmacy. Direct sales of prescription medication by a manufacturer to a pharmacy or chain pharmacy distribution center are also included within the normal distribution channel."

Under this concept, pedigrees are not required to be passed for prescription drugs that remain within the normal distribution channel. This approach treats each member of the prescription drug supply chain equally so long as they are purchasing and distributing prescription medication within the defined normal distribution channel.

While we recognize the normal distribution approach does pose minor enforcement challenges, we believe this approach provides a practical and immediate interim step to allow the industry sufficient time to research and develop a reliable electronic pedigree system.

To add another layer of security, we would also support a requirement that wholesale distributors be required to place a statement on invoices indicating that all drugs listed on that invoice were purchased originally from the manufacturer. Otherwise, the wholesale distributor would have to maintain on file an authenticated pedigree for that drug.

2. Education of Health Care Professionals

Alerting and educating health care professionals in a timely manner about counterfeit drug products is essential. NACDS believes that the Board of Pharmacy and the FDA should work with professional and trade associations representing the components of the

drug supply chain on these efforts. Real time exchange of information is the best way to communicate this information, given the potential negative public health consequences of not removing these products from the system in a timely manner.

Through an NACDS affiliate, ChainDrugStore.net, our members are working with FDA to provide an alert system for counterfeit products. ChainDrugStore.net is a secure, online communication vehicle that provides manufacturers, government agencies, and other third party information providers the ability to communicate directly with more than 200 retail chains, wholesalers and independent buying groups representing more than 52,000 retail pharmacies. ChainDrugStore.net can deliver communications on a national level, as well as target by jurisdiction and channel of business.

ChainDrugStore.net is a member of FDA's Counterfeit Alert Network. ChainDrugStore.net can deliver critical information to its entire audience within an hour of notification, whether from FDA, or directly from a manufacturer. This system could be enhanced to deliver similar information from the Board of Pharmacy. Many chains provide information from ChainDrugStore.Net down to the pharmacy level, providing a quick, reliable way to inform practicing pharmacists about counterfeit products, diverted products, or recalled products.

3. Drug Importation and the Black Market

No discussion about the problem of counterfeit drugs would be complete without addressing consumers' accessing prescription drugs from outside the legitimate drug supply chain, such as from foreign sources and through unscrupulous Internet-based vendors. FDA officials have stated that incidences of counterfeit drugs in the legitimate drug supply chain are rare, and that we can have no confidence in the safety or validity of a drug purchased outside the legitimate drug supply chain.

Importation of drugs for personal use from foreign countries poses a serious threat to the health and safety of Americans. Drug importation via unregulated Internet sites and/or "store fronts" in the United States offers a significant and growing avenue for counterfeit drugs to enter the country. The initiatives that we adopt to strengthen our closed drug distribution system will be in vain if consumers are continuing to access prescription drugs from these illegitimate sources. Greater licensing of wholesale distributors, drug pedigrees, and other proposals will not prevent counterfeiting if counterfeiters are allowed to mail their products directly to consumers from domestic operations and foreign countries.

We strongly encourage the Board of Pharmacy to enforce the current laws against drug importation by non-manufacturers. We also urge the Board of Pharmacy to continue to educate consumers about the threats to their own personal safety resulting from personal importation of drugs from other countries. In addition to being told that this practice is illegal, consumers may not be aware that this practice is also dangerous and potentially life-threatening.

RFID Adoption and Standards Development

As stated above, the Board's ultimate goal should be the adoption of RFID technology for electronic pedigrees; however despite the best efforts of all stakeholders, RFID technology is not yet widely available. To assist the Board in understanding the current status of RFID technology, as well as the existing challenges and obstacles, we would like to share with the Board information taken in part from testimony that NACDS submitted to the FDA in February 2006. That information is presented below in paragraphs numbered 1-6.

1. Incentives for RFID Adoption

The advocacy of the California Board of Pharmacy is a powerful incentive for RFID adoption. The Board's support of point-to-point pedigree communication among trading partners and the inclusion of the NDC in the EPC would encourage adoption, especially among community pharmacies.

2. Obstacles to Widespread RFID Adoption

a. RFID Standards

There are a number of significant obstacles to widespread adoption of RFID. First and foremost, there are no industry standards for RFID in the drug supply chain. While much progress has been made towards the adoption of RFID standards, we don't have standards in place today. If we look at the three approaches to RFID pilots from the recent FDA workshop, the manufacturers are using two different frequencies. Moreover, the two manufacturers that are using the UF frequency are using two different ISO standards that were not developed pursuant to drug supply chain requirements. In addition, the system must be interoperable across the prescription drug supply chain, meaning that the system should work no matter what tag a drug manufacturer puts on the product or what type of readers the downstream drug supply chain partners use. Community pharmacy does not have the ability or resources to purchase and support multiple technological approaches.

Currently there is no agreement on the data communication standard. The industry has developed requirements for an item level tag, but we have not yet heard back from the technology providers if they can develop products and services that will meet these requirements. Nor have these requirements been turned into a prototype that can be tested and piloted.

b. Pedigree Standards

There is no uniform standard for pedigrees. If a pedigree is at the item level, then we must have a single standard pedigree or standard data elements. Products pass through a number of states while traveling through the drug supply chain. Each state could require different pedigree elements resulting in delays, difficulties, and increased costs to pharmacies and wholesalers to distribute the drugs across the supply chain. To enable a

reasonable pedigree system, we need uniformity so that compliance is as efficient and as least costly as possible, and without costly interferences and delays. Additionally, as we move to an electronic pedigree, there must be a requirement that all pedigree software be interoperable. It is unreasonable to expect that a pharmacy should have to support multiple software solutions to receive drug products.

c. Costs of Implementation

Community pharmacy operates on a small and declining net profit margin, industry averages are between 2%-3%. We cannot afford to invest in a technology before it is mature and proven. RFID is a moving target at this time, with unsure frequencies, lack of standards, and performance issues. Until the technical performances of an RFID-based e-pedigree system have been proven, the technology has been presented to community pharmacy to allow for analysis of operational impacts and analysis of financial costs and benefits, community pharmacies will be unable to invest their limited resources. Moreover, it makes little sense for pharmacies to invest in the technology until a significant percentage of the drug products that they receive are equipped with RFID tags.

d. Business Issues

Community pharmacies have serious concerns about data sharing with respect to e-pedigree and RFID in the drug supply chain. Our industry needs time to study the potential impact of data sharing and determine how or if sharing product movement information in real time can benefit all members of the drug supply chain.

Another business concern is liability when an RFID tag cannot be read after it enters the drug supply chain, and what should be done with a drug product with a faulty tag. Millions of dollars are potentially at risk if tag read rates are not 99.999%. How this issue is ultimately decided will affect product availability and patient safety.

We urge the Board of Pharmacy to monitor industry actions, not only in the development of RFID technology, but also to understand the various initiatives that industry has undertaken, to engage in a regular dialogue with industry stakeholders regarding these efforts, and to listen to stakeholders beyond the technology vendors who have different incentives than members of the drug supply chain with respect to the readiness and feasibility of e-pedigree technology solutions. It is extremely important for the Board of Pharmacy to recognize that while much work remains before any widespread adoption of RFID, industry stakeholders are taking practical and immediate steps to further improve the integrity of the U.S. drug supply. The Board of Pharmacy should encourage these steps and engage in a regular dialogue with industry stakeholders regarding other practical and immediate steps that can be taken.

3. Timetable for Industry Adoption

Simply stated, there can be no definitive timetable established for industry adoption of RFID until national standards are developed and are available and interoperable across the drug supply chain. Concurrently more work needs to be done (through pilots) to create a suite of solution components that will address the disparate needs, resources and capabilities of the community pharmacy industry – from the independent pharmacies to a 6,000 store chain.

At the recent FDA workshop it was suggested that a "phased-in" approach for high-risk products would speed up implementation. While certainly this approach makes practical sense for a manufacturer given their implementation costs could be spread over a longer period of time, community pharmacy would still be required to be fully operational on day one. This puts an undue burden on the one participant of the drug supply chain that does not have price elasticity to cover their costs of implementation and requires community pharmacy to meet a deadline that manufacturers themselves cannot meet – complete implementation of RFID.

4. Standard Setting Body

We believe that EPCglobal is the appropriate body for RFID standards development; they have an approach that is industry driven and is consensus based. They have processes in place for standards to be amended once they are established based on new capabilities or new drug supply chain needs. Our only concern is that the cost of EPCglobal membership may discourage broader industry participation, especially by community pharmacies.

The Board of Pharmacy's continued involvement and guidance on e-pedigree issues will allow the industry to move forward. The Board can further the standard setting process by highlighting the urgency for standards and supporting standards that will fairly address the perspectives and realities of all segments of the drug supply chain.

5. Data Management

Our members have indicated that for a variety of reasons that a peer-to-peer distributed approach would work best for them. We already have an existing, secure electronic relationship with our trading partners. A peer-to-peer model would allow for faster adoption and would eliminate unnecessary costs for all drug supply chain participants. The peer-to-peer model is also more reliable. Even with the credit card systems that have been in place for years, we find those systems have slow times as well as times when their servers are unavailable. There is a genuine concern that a central database system similar to credit card systems will add unnecessary costs and, in those cases where access to the database is unavailable, negatively impact patient safety.

6. Privacy and RFID

Community pharmacy is very concerned about patient privacy. We cannot support a system where our patients' privacy could be infringed upon. Having said that, we believe that there are many opportunities to protect patient privacy in the RFID system. First and foremost, it should be noted that the vast majority of prescriptions (80+ %) are not dispensed in the original bottles from the manufacturer.

For the 15%-20% of the products that do utilize unit of dispensing packaging, privacy protection can be built into the tags and readers, not the numbering system. Additionally, the frequency of the tag being used can also provide additional privacy as read ranges can be rather minimal, less than six inches. Tag and reader manufacturers are also aware of this requirement and are developing techniques to ensure that privacy concerns are built into the system.

Additionally, through EPCglobal, we are commissioning a project to look at patient concerns with privacy, both for specific disease states as well as for the public in general. This project will help us develop privacy guidelines for drugs.

The Board of Pharmacy can play a role in privacy by providing guidelines for drug manufacturers for RFID tag placement as they begin to tag their products. Current efforts appear to place the tag behind the label. This does not allow a pharmacy to disable or remove the tag before dispensing. Any advice the Board can provide to drug manufacturers to make them aware that there is a need for community pharmacy to have the option of removing the tag would be helpful.

Conclusion

We very much appreciate the opportunity to provide our perspectives on the counterfeit drug problem and to recommend solutions to deterring the introduction of counterfeit drugs into the legitimate drug supply chain. We look forward to continuing our work with the Board of Pharmacy, with the FDA, and with our drug supply chain partners in assuring the safety and integrity of our drug distribution system.

RFID technology is still relatively new and unproven with respect to addressing drug counterfeiting and being a viable solution for e-pedigrees. Much still remains to be learned and decided. Standards must be adopted. Business issues must be resolved. Obstacles must be overcome. Costs must be determined and assessed. RFID technology remains a possible long-term solution.

We must ask the Board of Pharmacy to delay the requirement of electronic pedigree. We ask the Board of Pharmacy to consider the practical and immediate steps that have already been taken by community pharmacies, wholesale distributors, manufacturers, and the various state governments. Finally, we ask the Board of Pharmacy to consider the greater protection that can be provided by adopting the concept of the "normal

distribution channel," especially in light of the unresolved issues that are associated with any electronic pedigree system.

The community pharmacy industry consists of companies of varying sizes and technical capabilities. Our members range from the largest company in the world to others that have as few as four stores and a little over $10 million in total annual sales. As we look for solutions that can be adopted by our industry, we need to recognize that not all companies have resources, be it financial, technical, or human, to be at the leading-edge of the technology curve. As the Board looks at potential technology solutions, we strongly urge you to consider that members of our industry have varying levels of resources, and that for a technology solution to work it must utilize nationally recognized and accepted standards, have been tested and proven to function, as well as be cost-efficient, and easy to implement.

Sincerely,

Kevin N. Nicholson, R.Ph, J.D.
Vice President, Pharmacy Regulatory Affairs
National Association of Chain Drug Stores

Bill Dombrowski
President
California Retailers Association

GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

Stanley Goldenberg
President
California Board of Pharmacy
1625 North Market Boulevard
Suite N219
Sacramento, CA 95834

Dear Mr. Goldenberg:

The Generic Pharmaceutical Association (GPhA) urges the Board of Pharmacy to postpone implementation of the state's prescription drug pedigree program for one year. GPhA represents the manufacturers of more than 90 percent of all generic drugs dispensed in the United States.

While the generic industry recognizes the importance of ensuring the integrity of the prescription drug supply chain, we believe that more time is necessary to ensure that a pedigree process can be properly and effectively implemented. Because many generic companies manufacturer numerous products – far more than most brand companies - the burden of implementing a pedigree program is greater for generic manufacturers than for brand manufacturers.

We are concerned that some manufacturers may not be able to fully implement such a program by January 2007. The result could be interruptions in supplies and reduced access to affordable generic drugs for residents of California. If some generic manufacturers were unable to participate in the pedigree program, the competitive marketplace for generic drugs could also be disrupted. The unintended consequences could be increased prices or less availability of generics.

In the interim, we encourage the Board of Pharmacy to consider a limited test program focusing on prescription medicines that are more likely to be the subject of counterfeiting in an effort to ensure the feasibility of the program. Such a program would help to identify problem areas and allow the State of California an opportunity to make adjustments if needed without causing wholesale disruption of the dispensing of pharmaceuticals.

GPhA and its member companies stand ready to work with the State and the Board of Pharmacy as you move forward with this process. We appreciate the opportunity to share our thoughts and concerns with the Board.

Sincerely,

Bruce Lott

Bruce Lott
Vice President of Government Affairs

C.C./ John Benton, Terry McGann

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Associate Director, Trade
Biogen Idec, Inc.
14 Cambridge Ctr.
Cambridge, MA 02142

Ms. Patricia Harris
California Board of Pharmacy
1625 North Market Blvd.
Sacramento CA. 95834

3/15/2006

Dear Ms. Harris

Re: California Pedigree Legislation Bus and Prof 4034 and 4163 requiring manufacturers to provide Electronic Prescription Drug Pedigree.

With regards to the pending California legislation scheduled to begin January 1, 2007, requiring manufacturers to incorporate Electronic Prescription Drug Pedigrees, Biogen Idec is in full support of the 'spirit' of any legislation which would protect the integrity of the pharmaceutical supply chain from threats of 'counterfeiting' While Biogen Idec products have not knowingly been impacted by 'counterfeit threats' our company is very aware and concerned with the risks that such threats pose to the integrity of all drug products and most importantly to the safety of our patients.

Respectfully, Biogen Idec would like to lend our support to the proposal, which would extend the start date of this legislation from January 1, 2007 to January 1, 2008. This extension would allow all parties additional time to assess the various options available from a technology perspective as well as allowing for maximum compliance with the legislation.

Biogen Idec welcomes the opportunity to participate in future discussions with regards to this legislation.

With regards,

Matt Minczeski
Biogen Idec
Associate Director, Trade Development

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Global Regulatory Affairs
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847.473.6303

Baxter

Date: 03/14/2006

Ms. Patricia Harris, Executive Officer
California State Board of Pharmacy
1625 North Market Boulevard
Suite N219
Sacramento, CA 95834

Submission to Enforcement Committee Workgroup on Electronic Pedigree

Baxter Healthcare Corporation would like to thank the California Board of Pharmacy for providing an open forum for comment on the prescription drug wholesale distributor legislation and implementing rules. Baxter produces a wide range of prescription drugs that includes, intravenous drugs as well as specialty products, such as kits, that are a combination of a prescription drug and a delivery device. The pharmaceutical portfolio includes premixed antibiotic drugs, critical care generic drugs, anesthetic agents and parenteral nutrition products. Baxter also produces prescription drugs used for peritoneal dialysis and hemodialysis.

The following comment is intended to complement the substantial work already conducted by the Board relative to prescription drug pedigree requirements and the new wholesale drug distributor legislation. Accordingly, Baxter submits the following comments for inclusion in the administrative record:

(1) **Implementation of the California Electronic Pedigree Requirement**:

a. Proposed Alternatives to the Requirement:
While every effort is currently directed at achieving compliance with the pedigree rule in California by the required implementation date, Baxter believes that legitimate industry participants would benefit by a narrowing of the pedigree rule's applicability. To that end, Baxter is providing the Board with what it believes is an acceptable alternative to a broad rule.

The following concepts have previously been submitted to the US Food & Drug Administration in support of its current Anti-Counterfeiting initiative and provide, in pertinent part, as follows:

i. Susceptible Drug Listing Concept :
Baxter recommends that the Board utilize a list of most susceptible drugs and base the applicability of the prescription drug pedigree requirement on the prescription drugs contained in this list. Several states have considered, or are currently considering, such a model to clearly define the scope of their respective pedigree requirements. Baxter submits that such a list would be relatively easy to create based on the list formerly maintained by the National Association of Boards of Pharmacy (NABP) as well as other state sources. Additionally, this list could be easily updated by implementing routine monitoring of the prescription drug supply chain through post-market, suspected counterfeit drug data reporting/surveillance mechanisms.

Counterfeit drug operations thrive by selling drugs with high after-market popularity and national visibility. There are many drugs, including generic pharmaceuticals and intravenous solutions that are not a primary focus of counterfeit drug operations due to their low profit margins, lack of after-market popularity and the inability of users to abuse such products.

Applying the pedigree requirement to a specific list of drugs, a list that can be updated and revised as needed, renders the pedigree process more manageable for regulators and industry alike. The Board would be requiring pedigree information on those prescription drugs in which there is the most counterfeit interest while industry would not bear the burden of implementing pedigrees in all of their product families across all product lines. Baxter respectfully submits that this approach could be used as the defining threshold for when pedigrees will be required in all cases or, in the alternative, as an invaluable first step in a systematic, phase-in process.

ii. Normal Distribution Channel Concept:
In what was presumably an effort to diminish the burden on legitimate wholesaler operations, several states have enacted laws that require the creation or passing of a pedigree when a wholesale transaction falls outside of a statutorily defined "normal chain of distribution." While not entirely dissimilar to the concept of an authorized distributor of record, this is an overly simplistic view that does not take into consideration various common distribution scenarios currently employed by wholesale drug distributors and tries to capture only those few models thought to normally occur as a part of legitimate wholesale distribution activities.

To the extent the Board finds value in using a similar modality to define the scope of the pedigree requirements, Baxter supports a standard definition of "normal chain of distribution" provided that such definition includes a consideration of the distribution models currently employed in today's wholesale distribution scheme. Under this rationale, transactions falling within the realm of a pre-defined "normal chain of distribution" would be exempt from having to generate and pass pedigree information. Those transactions not specifically captured in the standard definition of a normal distribution chain would then have the burden of creating/passing pedigree.

In support of this position, Baxter provides the following transactions that it believes fall within the "normal chain of [wholesale drug] distribution" and thus should not require a prescription drug pedigree:

(i) Shipments from a prescription drug manufacturer to the end user by way of a third party logistics provider (3PL).
(ii) Shipments from a prescription drug manufacturer to a primary wholesaler by way of a 3PL provider.
(iii) Shipments from a prescription drug manufacturer to a primary wholesaler by way of a 3PL provider and subsequent shipment to a secondary wholesaler and then from the secondary wholesaler to the end user.
(iv) Shipments from the contract manufacturer of a prescription drug to the end user via 3PL.
(v) Shipments from a prescription drug manufacturer to the end user by way of a 3PL with a separate entity acting as a broker to the transaction.
(vi) Shipments from a prescription drug manufacturer to a wholesaler and subsequent shipment from the wholesaler to a hospital

pharmacy, clinic, or other location authorized to receive such shipments.

In order to eliminate confusion over industry terms and descriptions of various entities within the supply chain, Baxter encourages the Board to consider defining the various participants in today's various distribution scenarios as well. For example, Baxter recommends that the Board clearly define the role of a third party logistics provider (3PL). A proposed definition would consider a 3PL to be the following:

Any party that, by business arrangement or contract with the prescription drug manufacturer, does not participate in prescription drug order procurement, order receipt from a customer, customer servicing related to the order of that prescription drug or invoicing for the wholesale transaction or sale, but whose role in wholesale drug distribution is limited in scope to order fulfillment (i.e. picking, packing, shipping and delivery) of a prescription drug. Transactions involving 3PL providers do not result in a transfer of title to the 3PL of the prescription drug product being distributed.

Baxter also supports the incorporation of the Authorized Distributor of Record concept and evaluation of its foreseeable future use in defining "normal chain of distribution" transactions. Further, Baxter encourages the Board to continue to benchmark with industry participants to define and capture all of today's current, legitimate distribution models and incorporate the models, or the mechanisms thereof, into a standard definition of "normal chain of distribution."

Baxter is not aware of any statutory restrictions and/or limitations placed upon the Board's authority to implement actions such as those recommended above. To the extent authority is not grounded in existing legislation or to the extent that such limitations are expressly included in existing law, Baxter would support an initiative to amend existing statutory requirements.

b. <u>General Obstacles to Implementation of the California Pedigree Requirements</u>:

i. Generic Prescription Drug Manufacturers:

As stated earlier, counterfeit drug operations thrive by selling drugs with high after-market popularity and national visibility. Additionally, many generic drug manufacturers currently operate on profit margins markedly different from those manufacturers of popular, branded prescription drug products. Given this reality, many of the firms that will be affected by implementation of the rule may not have sufficient time to secure the financial resources needed to implement a robust and sustainable distribution integrity solution.

Although the State of Florida has not specifically set forth its reasons for proposing a delay in enforcement of its pedigree rules on generic drug manufacturers, the state has advanced a reasonable interim solution (not entirely dissimilar to a modified authorized distributor of record concept) that would alleviate some of the perceived burden placed on the generic industry by the pedigree rule.

Baxter recommends that the Board evaluate the impact to the generic drug market before the implementation period begins.

ii. Information Technology Concerns:
As the California rule for pedigree is inherently electronic, several concerns have arisen which may affect the ability of industry to comply with the implementation timeframe. Baxter has tried to highlight some of the concerns in pertinent part. Specifically, industry will need to be apprised of the following:

(1) Given that the California rule requires all electronic pedigrees and there will be a need for systems interoperability, whether the Board intends to accept the EPC Global XML Schema specification;
(2) Which entity will be designated by the Board as a Digital Certifying Authority;
(3) Which entity, if not the designated Digital Certifying Authority, will be responsible for digital certificate revocation;
(4) Whether serialization is the ultimately anticipated outcome for this process; and
(5) Whether the certification (signing using digital certificates) process may be automated or whether it must be consciously performed for each transaction by the signatory.

iii. Technological Advancement - Risk, Cost and Development Level:
Baxter believes that mandating electronic pedigree requirements by January 1, 2007 may unnecessarily hinder implementation by industry of subsequent technological advancements that have the capability to enhance existing software solutions or which render existing systems more robust. Specifically, some of the electronic pedigree software solution providers have yet to realize a product beyond its first version; an immaturity concern which alone could factor in as a substantial cost where anomalies are identified downstream (post-implementation). While there are providers with more mature products, the problem will still reside with industry over actual integration of the software solution with existing software interfaces and with current business practices.

Additionally, although the extent of counterfeiting operations in the US is presently unknown, it is readily acknowledged that the US has one of the safest drug supply chains in the world. Further, Baxter produced drugs have never been the subjects of known counterfeit drug operations. Implementation of new and relatively expensive technology to prevent their unauthorized duplication will only raise the cost of Baxter's prescription drugs to end consumers.

If the requirements are viewed then as precautionary measures to further secure the drug supply chain (as opposed to emergency mandates to combat a pervasive threat), it stands to reason that cutting edge track and trace service providers should be afforded the time to sufficiently develop robust products through research and testing prior to actual implementation. Baxter avers that a minimal delay in implementation would provide a maximum opportunity for market maturity of existing software solutions from both a technology advancement and cost reduction standpoint.

Lastly, Baxter respectfully requests that the Board take this information into consideration as it progresses toward balancing product concerns with cost concerns that will ultimately be passed to the end consumers. Baxter further suggests that a delay in implementation of the

requirements be maintained until the Board has been afforded the opportunity to study the availability and feasibility of all existing track and trace technologies and solutions.

iv. Federal Uncertainty – Pending Guidance:
By May of this year, the US Food & Drug Administration's task force for the Anti-Counterfeiting initiative will provide a final report to the Commissioner detailing next steps and guidance for the regulated industry. During a recent task force meeting, the Agency specifically sought information relative to state regulatory activity as well as industry-perceived obstacles to full adoption of various track and trace technologies. Citing numerous barriers to widespread implementation, industry representatives requested federal guidance and oversight for many of the activities currently regulated at the state level due to concerns over state-to-state consistency of legal requirements.

Baxter suggests that a stay of enforcement of the California rule would provide the necessary timeframe for federal regulatory authorities to assess their current regulatory framework and provide guidance as to current, and possibly changing, federal requirements which may impact how the states regulate wholesale drug distribution.

(2) **Workgroup on Electronic Pedigree**:
Baxter applauds the Board's decision to form a workgroup addressing the issues generated by the implementation of the pedigree rule. There is much diversity relative to distribution practices within the pharmaceutical supply chain. Baxter believes that by including the recommendations and perspectives from industry participants, this will prove invaluable as the Board works toward a common supply chain solution. Baxter encourages the Board to continue with initiatives that prevent illegitimate wholesalers from entering legitimate distribution channels as well as those that attempt to strike a balance with the burdens these requirements place on legitimate supply chain participants.

To the extent that the workgroup seeks additional input from industry participants in the wholesale drug distribution supply chain, Baxter would appreciate the opportunity to contribute to the committee as a standing participant.

(3) **Third Party Logistics (3PL) Providers – Pedigree Requirements and Licensing**:

a. Transfer of Title:
The statutory definition of "*pedigree*" states that a pedigree is required for "*each transaction resulting in a change of ownership of a given dangerous drug*" (*see generally* Section 4034, CA Business & Professions Code). Based on Baxter's interpretation, the phrase "*transfer of title*" appears to be the test for whether passing of pedigree is required.

The Board has published a document with a list of questions that the Board has received regarding the implementation of the pedigree requirement and proposed answers. Question 10 states, "*What types of "change of ownership" transactions require documentation on the pedigree.*" The proposed answer includes "*third party logistics transactions*" as a type of "*transfer of title*." As stated in the proposed definition *supra*, third party logistics transactions (3PL) by definition do not involve a "*transfer of title*." In those instances, a manufacturer compensates a 3PL to distribute its products. The transfer of title is from the manufacturer directly to the customer, be it a purchasing pharmacy or other distributor. The

Board may feel that those transactions should require transfer of pedigree, but Baxter submits that this interpretation is contrary to the plain meaning of the statute.

The US Food & Drug Administration, in its final report on anti-counterfeiting, did not recognize the use of third party logistics providers as a source or entry point for counterfeit drugs. Transactions involving shipments of prescription drugs from a manufacturer directly to a customer (pharmacy) are one of the most secure types of prescription drug distribution transactions from a counterfeit drug perspective.

For the reasons articulated above, (i.e. 3PL transactions are not a source of counterfeit drugs and manufacturer to 3PL to pharmacy transactions pose little threat of introducing counterfeit drugs into the drug supply chain), Baxter does not believe that pedigree should be required for transactions that consist of shipment from manufacturer to a 3PL and then to the customer/end user.

b. Licensure of Third Party Logistics Providers:
For reasons similar to those mentioned above, Baxter does not believe that third party logistics providers require licensure as prescription drug wholesalers. These entities function only as the distribution arm of a prescription drug manufacturer. If the Board requires awareness of third party logistics providers or seeks to regulate their conduct, Baxter suggests creating a separate license specific to such providers. Baxter strongly recommends that, should the Board decide to license third party logistics providers, the terms of such license should exempt the entities from the requirements for verified-accredited wholesale distributor accreditation (VAWD) for licensing.

(4) **Incidental Shipments - Exemption for *de minimus* shipping activities**:
Baxter requests that an exemption be created for incidental shipments of prescription drugs into the state of California. From a distribution standpoint, it is not unusual for shipments to be made into a given state from virtually every distribution center in the country. In many cases, the number of units of prescription drugs shipped from an out-of-state distribution center may be less than 1,000 units per annum. Upon a cursory review, such a distribution scheme is confusing no matter how minimal the occurrences. However, securing prescription drugs from the first available distribution center across an entire network of distribution centers provides the customer with the professional and prompt service they have come to expect from Baxter.

As an example of an existing exemption for incidental prescription drug shipments, the State of New York provides that a facility that shipping less than $10,000 of drugs into New York does not have to be licensed as a wholesaler. Following this same logic, Baxter recommends an incidental shipment exemption based on the number of units shipped into California annually.

To find in the alternative, distributors and third party logistics providers may find that each of their distribution centers has to be licensed in every single state in order to prevent a violation of state law from an incidental shipment of a small quantity of prescription drugs. While this initially seems to be a feasible option with relatively low administrative burden, this would not necessarily be the case. Where an entity is required to obtain a voluminous portfolio of licenses in order to ensure customer service, additional costs for personnel, planning, information gathering, monitoring

and maintenance would be incurred and thus could result in the passage of cost on to the consumer.

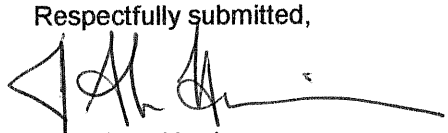
Baxter avers that distribution centers are arranged to service their customers quickly by shipping needed prescription drugs from the closest stocking distribution center, even if it is out of state. To that end, Baxter feels that it is the customers who should be accommodated to their expectations and without additional cost.

(5) **Product Labeling Activities**:
Baxter recommends that the Board consider implementing a rule allowing labeling activities related to pedigree to be performed in a licensed wholesale or third party logistics provider facility without being considered as manufacturing. As the Board already knows, the US Food & Drug Administration considers labeling part of the manufacturing process and thus can only be performed in a facility registered as a drug manufacturing establishment. The purpose for this proposal is to allow product manufactured outside of the United States to be pedigree-labeled at the United States distribution point for the drug.

In summary, Baxter Healthcare Corporation urges the California Board of Pharmacy to closely evaluate its comments as they are specifically intended to support the working group's current efforts to secure California's drug supply chain. Additionally, Baxter believes that by addressing the concerns and solutions noted in this memorandum, the legitimate participants in the wholesale drug distribution industry as well as the end consumer will ultimately benefit.

By submitting this regulatory comment, Baxter is indicating its willingness to work with the Board in any way deemed acceptable by the Board and/or to discuss, clarify or expand on the suggestions provided in this comment.

Respectfully submitted,



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March 14, 2006

Ms. Patricia Harris
Executive Officer
Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

Re: Electronic Pedigree Implementation Date

Dear Ms. Harris:

The Food Marketing Institute's (FMI) members are concerned that the supply chain will not be able to adequately prepare to meet the rapidly approaching effective date for electronic pedigree, and we are writing to support the January 1, 2008 extension, as provided for under § 4163.5. FMI appreciates the opportunity to comment on this matter.

FMI is a non-profit association that represents food retailers and wholesalers, as well as their customers, in the United States and around the world. Association members operate approximately 26,000 retail food stores with close to 15,000 in-store pharmacies. These in-store pharmacies account for nearly 20 percent of all outpatient prescription drugs dispensed in America. FMI's retail membership is composed of large multi-state chains, regional companies and independent grocery stores.

Our members are concerned with the numerous challenges associated with implementing electronic pedigrees for prescription drugs and feel that a one-year delay would be beneficial to both industry and the Board of Pharmacy. We strongly urge the Board to extend the implementation date until a uniform, track and trace electronic solution can be developed.

As you know, the delay on the effective date of the pedigree provisions in the federal *Prescription Drug Marketing Act* (PDMA) expires December 2006. The Food and Drug Administration (FDA) recently held a Counterfeit Drug Task Force Public Workshop to receive comments on the *Act*. During this meeting, it was suggested that FDA create uniform standards for pedigree implementation so that an interoperable system could be created to assist the states. A delay would give FDA time to create additional guidance for states and/or modify PDMA.

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

CALIFORNIA RETAILERS ASSOCIATION

January 30, 2006

Ms. Patricia Harris
California State Board of Pharmacy
1625 North Market Blvd, Suite N 219
Sacramento, CA 95834

Dear Ms. Harris:

RE: Implementation of the Electronic Pedigree Requirement for Prescription Drugs Effective January 1, 2007

Introduction

On behalf of our 31 member companies operating approximately 3,122 chain pharmacies in the State of California, the National Association of Chain Drug Stores (NACDS) would like to share with the California State Board of Pharmacy ("Board") our concerns about the pending implementation date of January 1, 2007 of the electronic pedigree requirement for prescription drugs.

We have grave concerns that January 1, 2007 is an unrealistic compliance date for the entire pharmaceutical supply chain, from manufacturers to pharmacies and every entity between, to implement and comply with the requirements of an electronic pedigree. Moreover, we believe that the requirements are overly broad and unnecessarily burdensome, and should be amended so that the requirements are reasonable while still ensuring that counterfeit pharmaceuticals do not enter the pharmaceutical supply chain. Ideally, these amendments should be adopted through additional legislation. However, we believe that the Board may adopt the necessary amendments through rulemaking.

Including California, twelve states have adopted legislation requiring pedigrees for prescription drugs. However, no state has imposed requirements as broad and far-reaching as California. The Florida legislature was the first state to adopt pedigree requirements, in 2003. The Florida legislature originally passed overly burdensome pedigree requirements. However, both state officials and the regulated industries have worked together through countless face-to-face meetings, conference calls, emails, and one-on-one telephone calls to implement a workable pedigree system that will become operational by July 1, 2006. While the Florida pedigree system is not ideal, and we do not recommend that California adopt the Florida system, we do appreciate Florida state

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officials' willingness to work toward achieving a workable pedigree system. It is our hope that the California Board of Pharmacy would do the same.

"Normal Distribution Channel"

Many other states have passed pedigree legislation that we believe is more reasonable while still ensuring that counterfeit products do not enter the pharmaceutical supply chain. A provision we recommend is the concept of a "normal distribution channel," which has been adopted by states such as Arizona, Oklahoma and Texas. Moreover, this concept is almost universally supported by the regulated industries: manufacturers, primary wholesalers, and pharmacies. NACDS has developed a model definition of normal distribution channel:

"Normal distribution channel means a chain of custody during distribution of a prescription drug that goes from a manufacturer to a wholesale distributor to a pharmacy to a patient or a chain of custody for a drug that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intracompany pharmacy to a patient. Direct sales of prescription drugs by a manufacturer to a pharmacy or a chain pharmacy warehouse are within the normal distribution channel."

Coordinating with the concept of the normal distribution channel is the requirement that a pedigree must be passed only when a prescription drug goes outside the normal distribution channel, that is, to an entity such as a secondary wholesaler. These concepts work because the entities that comprise the normal distribution channel are trusted entities; the additional documentation as to source (i.e. pedigree) is not necessary unless the prescription drug is from a source outside this chain of trusted entities. To add additional layers of security, we would support requirements that within the normal distribution channel, invoices must include a statement that the product was purchased directly from a manufacturer. This requirement provides the pharmacy with assurances that the product is within one transaction from the manufacturer. All other scenarios would require a pedigree.

We are aware that CA Bus & Prof §4163 requires that a wholesaler or pharmacy may not sell, trade, or transfer a prescription drug at wholesale without providing a pedigree, nor may receive a prescription drug without receiving a pedigree. However, we believe that the Board has the authority to exempt entities within the normal distribution channel from these requirements. If the Board does this, then the pedigree requirements would apply when a pharmacy or wholesaler sells, trades, or transfers a prescription drug to an entity that is outside the normal distribution channel, or receives a prescription drug from outside the normal distribution channel. We ask that the Board refer this matter to your legal counsel for an opinion.

In the alternative, if the Board's opinion is that it does not have the statutory authority to exempt from the pedigree requirements those entities within the normal distribution

channel, then NACDS and our member companies would support a legislative effort to amend the requirements of CA Bus & Prof §4163.

Impact Upon Generic Drugs

Finally, we are concerned about the impact a January 1, 2007 pedigree requirement may have upon the generic prescription drug market. The majority of generic drug manufacturers operate on very slim profit margins. Consequently, they may not have the financial resources to implement electronic pedigree technology for their products within the next few months. Moreover, many of them have not even started to think about providing an electronic pedigree and/or adding RFID technology to their products. We believe that these factors will cause many generic drug manufacturers not to be able to meet the January 1, 2007 deadline, and will therefore be shut out of the California market. The unfortunate result would be less generic drug availability, less competition, and higher prescription drug prices for California residents.

We ask the Board to consider the impact of a January 1, 2007 pedigree requirement on the generic drug market, in addition to our recommendations with respect to the normal distribution channel. We recommend a delay in the effective date of the pedigree requirement, as well as recognition that pedigrees are not required within the normal distribution channel.

Thank you for your consideration of these comments.

Sincerely,

Kevin N. Nicholson, R.Ph, J.D.
Vice President, Pharmacy Regulatory Affairs
National Association of Chain Drug Stores

Bill Dombrowski
President
California Retailers Association

ATTACHMENT D

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

Workgroup on E-Pedigree
March 16, 2006

Red Lion Hotel
1401 Arden Way
Sacramento, CA 95815

Present: William Powers, Chair, and Board Member
Stan Goldenberg, R.Ph.. Board President and Member
Dave Fong, PharmD., Board Member

Staff: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room, Liaison Counsel, Deputy Attorney General
LaVonne Powell, Staff Counsel

Call to Order

Chair William Powers called to the meeting to order at 9:30 a.m. He welcomed the many participants and explained that the purpose of the Workgroup on E-Pedigree was to bring all the stakeholders together to discuss the implementation of the electronic pedigree requirement that will take effect on January 1, 2007.

Presentation on California's Requirements

Supervising Inspector Judi Nurse gave a brief overview of California law regarding the electronic pedigree requirement. She explained that in 2004, the Board of Pharmacy sponsored legislation, SB 1307 (Chapter 857, Statutes of 2004) that became law in 2005. The bill made various changes to license requirements of wholesalers and the distribution of dangerous drugs in California. Most of the licensing requirements became effective in 2006 and the pedigree requirement becomes effective January 1, 2007

Ms. Nurse reported that the law authorizes the Board of Pharmacy to delay implementation of the pedigree requirement until January 1, 2008, if the board determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of the prescription drug within the state. The California legislature may extend the date for compliance with requirement for a pedigree for pharmacies if it determines that it is not yet economically and technically feasible for pharmacies to implement electronic technologies to track the distribution of prescription drugs within California. She presented the definition and requirements for an electronic pedigree and the prescription drug information that must be tracked.

She gave an overview of the transaction source and information that must be recorded on the pedigree each time a prescription drug changes ownership and the requirement that the information on the pedigree must be certified as true and correct.

Ms. Nurse explained that the other provisions of law as it relate wholesalers and pharmacies. All wholesale distributors selling prescription drugs into California must be licensed in California as of January 1, 2005. As of January 1, 2006, all licensed wholesale distributors must have a surety bond. Beginning January 1, 2007, a wholesale distributor or pharmacy may not purchase, sell, trade or transfer a prescription drug without receiving or issuing a pedigree. In addition, pharmacies may only furnish prescription drugs to: wholesale or manufacturer from whom drugs are acquired, a licensed wholesale reverse distributor (as defined in B & P § 4040.5), to a pharmacy or wholesale distributor in sufficient quantity to alleviate a specific shortage, a patient or pharmacy pursuant to a prescription, health care provider authorized to purchase prescription drugs and to a pharmacy under common control.

Ms. Nurse provided the restrictions that are limited to manufacturers and wholesale distributors in that they can only furnish prescription drugs to a licensed business or prescriber, can only acquire prescription drugs from manufacturer or licensed wholesaler, and starting January 1, 2007, a wholesaler or pharmacy may not sell, trade or transfer a prescription drug without a pedigree.

State of E-Pedigree and EPC/Radio Frequency Identification (RFID) Standards

Mike Rose from Johnson and Johnson and Ron Bon from McKesson as Co-Chairs of the EPCglobal Healthcare and Life Sciences Business and Action Group presented on the state of electronic pedigree and RFID standards.

EPCglobal US™ is a subsidiary of GS1 US (formerly the Uniform Code Council) serving subscribers in the United States to help foster the adoption of EPC Global Network and related technology. The EPCglobal network combines radio frequency identification (RFID) technology, existing communications network infrastructure, the Electronic Product Code™ (EPC, which is a number for uniquely identifying an item) to enable accurate, cost-efficient visibility of information in the supply chain. EPCglobal community represents 30 of the top 40 pharmaceutical manufacturers, which includes 16 of the top 20 US manufactures, 3 of the 4 top retail pharmacies and 4 of the top 6 supermarket pharmacies (20,000 locations in total) and 4 of the top 5 medical device companies.

In 2004, the EPCglobal Healthcare Action Group was formed to address the following critical needs: pedigree management (including a pedigree messaging standard), air interface standard for item level tagging, serialization (the format of the EPC on the tag), decommissioning of tags and network security. EPCglobal also helped form and supports the Unified Pedigree Coalition.

While the presentation focused on Radio Frequency Identification technology (RFID) technology, it was explained that the standards that were developed are for any electronic pedigree. However, EPC/RFID was chosen because shipments can be read and authenticated with no "line of sight" needed. It is anticipated that RFID will the method used to track a drug's pedigree. The manufacturer would tag the drug with a small chip and antenna. When the tag is in close proximity of a reader, it would receive a low-powered radio signal and interact with a reader exchanging identification data and other information. Once the reader receives data, it would be sent to a computer for processing.

Wholesale distributors and pharmacies can confirm inbound receipts of item level products, expired items can be identified without handling each item, pallets and cases can be received without disassembly and there is a reduction in physical handling which equates to a reduction in risk and increased security. EPC also takes advantage of best practices for data sharing in that the owner holds the distributed data and there is a lower cost to the supply chain. It was noted that current EPC implementations by global leaders indicate a long-term commitment. RFID has the capability to solve critical regulatory issues. However, not all products are RFID candidates such as biologics, proteins, metal and glass. The tag and reader prices are coming down and there are pilots underway that will contribute to the efforts to establish standards.

The E-Pedigree standard addresses two key challenges in the pharmaceutical industry in that it provides a universal interchange format to express pedigree requirements of varied state regulations as drug products flow from one state to another and it enables trading partners to send and receive pedigrees in a secure and interoperable manner that leverages business to business technologies and processes. The E-Pedigree standards process requires that each party engaged in the wholesale distribution of prescription drugs must provide a pedigree to the recipient for sales, returns, and transfers of prescription drugs, pedigrees must contain a certification (via signature) by the sender that the information is true and accurate, pedigrees must be authenticated by the recipient prior to receipt of the drugs, recipient must add receipt and authentication to the pedigree, and a pedigree received by or provided by an organization is subject to recordkeeping requirements for record retention and availability.

The E-Pedigree interchange standards establish a format that meets federal PDMA standards and state requirements; it also has an extensible format that supports future state requirements. The standards also support regulatory and business requirements in that it tracks serialized items, repackaged products, sales, transfers, and return transactions. It can create an electronic pedigree from paper pedigree and it supports digital signatures and electronic authentication. It also enables interoperability among trading partners in that there is representation of pedigrees in a common portable format and there is an exchange of data using existing business data transfer

mechanisms. It also supports standard security protocols such as public key infrastructure.

The E-pedigree standards establish the requirements for the process, format, data elements, interchange, signatures and authentication. The E-pedigree interchange standards have been completed that meets the federal and state needs, addresses regulatory and business requirements, and enables interoperability among trading partners

The challenges to industry included data sharing issues, non-serialized items, patient privacy, public policy, regulatory considerations, cost/benefits differences by stakeholder, end-to-end supply chain implementation which is essential for mass adoption, and a lack of an universal pedigree agreement. The technology challenges were serialization, tag frequency, performance, package size, physical characteristics and event vocabulary.

E-Pedigree Pilot Programs
Viagra RFID Pilot Program

Walt Slijepcevich, Director of Pharmacy Development for Pfizer presented Pfizer's Viagra RFID pilot program. He stated that it is a pilot program aimed at shipping RFID/EPC tagged Viagra and creating an authentication capability by the end of 2005. Viagra was selected because it is Pfizer's most frequently counterfeited product and now all Viagra produced for sale in the U.S. has an RFID/EPC tag. The key objective of the pilot program was to learn more about mass serialization and RFID technology and the business processes that are required. He explained the capabilities that RFID created and the key decisions that needed to be made. The next phase of the pilot project is to determine how to handle data and exception reporting, learn more about wholesaler and pharmacy needs, understand the business process implementations and determine ongoing costs.

To implement RFID, there must be a commitment of others in the distribution channel, continued collaboration to obtain real world experience with RFID and mass serialization throughout the distribution channel (which is a significant investment), feedback on performance and utility of RFID-tagged product under normal day-to-day use, understanding of benefit and effect of targeted or total employment of mass serialization/RFID, resolution of data access and sharing, feasibility of tagging all pharmaceuticals and standards decisions and cost effective, robust tags.

The timetable provided indicated that there are numerous issues that must be addressed before a specific timetable for widespread adoption can be adopted. The key questions that need to be answered are: How will data be shared and who will have access? Do all pharmaceuticals need to be serialized and tagged for anti-counterfeiting purposes? How does the technology perform? Can costs be reduced? For an implementation timetable, it is Pfizer's position that there be two phases. Phase 1 would require tag only for "high-risk" products for adoption in the near future. Phase 2 would require a RFID tag on all items, which would be several years away and would be involve a substantial investment.

Pfizer supports the process used by EPCglobal in that the established standards are driven by business requirements and specific to the pharmaceutical industry. However, broader participation is needed from community and hospital pharmacy and while standards are under

development, guidelines on issues of privacy, EPC numbering schemes, and frequencies need to be developed.

Concern was expressed that an electronic solution may not be an immediate fix and the implementation of an electronic pedigree involving mass serialization may be many years off. However, to address immediate needs of securing the distribution system would be to require a pedigree when the chain of custody of a drug product does not go through the "normal distribution channel," which means the prescription drug goes from the manufacturer to a wholesale distributor to a pharmacy.

Mr. Slijepcevich concluded his presentation by stating that Pfizer is committed to the following initiatives in 2006, which are: McKesson On Track project and working with trading partners to address RFID implementation, Healthcare Distribution Management Association (HDMA) data management/sharing project, EPCglobal standards setting activities, developing Pfizer's own internal pedigree compliance solution, and Viagra RFID assessment and sharing lessons learned with the industry.

Use of RFID

Bob Dufour, Director of Pharmacy, Professional Services and Government Relations for Wal-Mart Stores presented its experience with RFID, which began in 1999 with trials in general merchandise and food products. In April 2004, the initial pilot began with 8 suppliers and one distribution center. By 2007, the pilot will include over 100 Wal-Mart stores and clubs, 5 distribution centers and 300 suppliers. To date, Wal-Mart has received 230,000-tagged pallets, 9 million tagged cases and over 90 million EPC reads.

Mr. Dufour presented slides of the pharmacy RFID program that showed the readers and scanning process. He stated that the milestones needed to expedite adoption included: the development of a single industry direction, developed business plans to simplify implementation, unified frequency standard and universal pedigree requirements.

Implementation of E-Pedigree

At the Enforcement Committee meeting of December 2005, a question and answer document was prepared and provided to all interested parties. Based on the discussion at that meeting and other questions that were submitted, the document was revised. Questions with a shaded background identified those questions that were new or that had been revised from the original December document. The document was marked "draft" because it is a work in progress and is intended for discussion purposes as the Board of Pharmacy is seeking input from all stakeholders.

Deputy Attorney General Joshua Room, Liaison Counsel for the board, commented that many of the subsequent questions that the board received addressed the issue of "change of ownership." He answered that in the sample questions and answers, the board provided examples of transactions that do or may constitute a "change of ownership." It is neither a comprehensive list nor does the inclusion of a transaction type on the board's list mean that in every case such a transaction creates or constitutes a "change of ownership." Except where the board is aware that

certain transfers of possession do not constitute changes in ownership, the board begins with the presumption that change in possession indicates a change in ownership. But that is not always the case and that presumption can be rebutted. What is significant is not whether a transaction fits a type identified by the board as presumably constituting a "change of ownership," but whether an actual change of ownership has occurred. He stated that "possession and risk" are strong indicators of ownership.

Mr. Room also explained that while a particular transfer/transaction may not need to be recorded on the pedigree, the record-keeping requirement for acquisitions and dispositions is separate from and additional to the pedigree requirement. The transferring entity must still provide the pedigree (recording the transactions to that point) to the transferee, and the transferee (and/or the first entity) must still provide that pedigree to any subsequent transferee.

The pedigree is considered part of the records of acquisition and/or disposition of any prescription drug that are required to be maintained and immediately retrievable for inspection (e.g. per Section 4081 and 4105) wherever the prescription drug may travel or be stored. If a particular transfer of possession does not result in a transfer of ownership, it may not need to be recorded on the pedigree. However, it will still be necessary for the pedigree to transfer to any entity (person) taking possession, for record-keeping purposes.

It is not the board's intent to answer hypothetical questions or determine how licensed entities must comply with the law.

It was asked whether prescription drugs that have expired and are not resalable require a pedigree when returned to a wholesaler, reverse distributor or manufacturer. A pedigree is required as part of the records of acquisition and/or disposition of any prescription drug by a wholesaler and pharmacy. If the transaction is considered a "change of ownership" then the transaction must be recorded on the pedigree. It was also asked about situations where a pharmacy purchases another pharmacy and its prescription drug inventory or a pharmacy purchases the inventory of a pharmacy that is closing. The purchase of the inventory may be considered a change of ownership and may require that it be recorded on the prescription drug pedigree.

Implementation Date of E-Pedigree – January 1, 2007

Business and Professions Code § 4034 and 4163 become operative on January 1, 2007, and as of that date prohibit any wholesale sales, trades, or transfers of prescription drugs, or any acquisitions of prescription drugs, absent a pedigree recording and accompanying the transaction. Pursuant to Sections 4163.5 and 4163.6, this prohibition and/or the requirement of a pedigree may be delayed by the Board of Pharmacy until January 1, 2008, upon a demonstration of need by the industry, and the by the Legislature (for pharmacies) until January 1, 2009.

The law as enacted does not contemplate a phased implementation, or application only to particular drugs.

The board has received requests for delay in implementation. At the September 2005 Enforcement Committee meeting, Lew Kontnik, Director of Brand Protection/Business

Continuity for Amgen demonstrated the challenges that Amgen has encountered in developing an electronic pedigree and the implementation of RFID to track its liquid products. At the conclusion of the presentation, Mr. Kontnik stated that it his company's position that it will be extremely difficult to meet the January 1, 2007 deadline.

In addition, the board has received letters from the Food Marketing Institute (FMI), National Association of Chain Drug Stores (NACDS), Biogen Idec seeking a delay in implementation to January 1, 2008, because of concerns that it is an unrealistic compliance date for the entire pharmaceutical supply chain, from manufacturers to pharmacies to implement and comply with the requirements of an electronic pedigree.

It was expressed that twelve states, including California, have adopted legislation requiring pedigrees for prescription drugs. However, no state has imposed requirements as broad and far-reaching as California. It was suggested that California consider as the other states have a provision that recognizes a "normal distribution channel." "Normal distribution channel" means a chain of custody during distribution of a prescription drug that goes from a manufacturer to a wholesaler distributor to a pharmacy to a patient or a chain of custody for a drug that goes from a manufacturer to a wholesale distributor to a chain pharmacy warehouse to their intercompany pharmacy to a patient. Direct sales of a prescription drugs by a manufacturer to a pharmacy or a chain pharmacy warehouse are within the normal distribution channel. Therefore, a prescription drug that is distributed through the "normal distribution channel" would not be required to have a pedigree.

It was noted that the "normal distribution channel" concept was considered during the legislative process, but was not accepted by the board. The problems with a "normal distribution channel" or "authorized distributor" approach include the difficulty of monitoring and enforcing such relationships. Whereas it is possible for board inspectors and staff to identify and verify an e-pedigree, they are not experts in contract law and able to reliably analyze contractual relationships between manufacturers, wholesalers, and pharmacies, such as would be necessary to verify claimed exemptions from e-pedigree requirements based on "normal distribution channel" or "authorized distributor" relationships. Moreover, where status as a "normal distribution channel" or "authorized distributor" depends on private-party designations as such, the board lacks the ability to effectively monitor such designations. These relationships can change without notice, and often out of the view of the board. And furthermore, adopting a "normal distribution channel" or "authorized distributor" approach would presumably exempt a huge number of transactions from being part of the e-pedigree tracking system, which is inimical to the intent of the statute. This would take those transactions out of the verifiable e-pedigree domain, and increase the temptation for individuals, including even the employees of those "authorized distributors," to take advantage of this lack of oversight. The risk is too great. The e-pedigree is a far more reliable method of tracking the flow of drugs.

Concern was also expressed regarding the impact of the pedigree requirement may have on the generic prescription drug market. The majority of generic drug manufacturers operate on very slim profit margins. Consequently, they may not have the financial resources to implement electronic pedigree technology for their products in the next few months.

Other alternatives included establishing a list of the most susceptible prescription drugs and require a pedigree for only those drugs on the list. Provide exemptions to wholesalers that distribute incidental shipments of prescription drugs into California and exempt Third Party Logistics Providers from licensure as wholesalers.

It was also noted that the delay on the effective date of the pedigree provisions in the federal Prescription Drug Marketing Act (PDMA) expires December 2006. The federal Food and Drug Administration (FDA) held a Counterfeit Drug Task Force Public Workshop in February 2006 to receive comments. It was reported that the task force for the Anti-Counterfeiting initiative plans to issue its final report to the Commissioner in May. During this meeting it was suggested to the FDA that it create uniform standards for pedigree implementation so that an interoperable system could be created to assist the states. A delay by the board would give the FDA time to create additional guidance for states and/or modify the PDMA.

The Enforcement Committee acknowledge the tremendous amount work that the industry has done nationwide to implement the electronic pedigree requirement and while much of the discussion focused on why compliance could not be met by January 1, 2007, the committee asked the stakeholders to set forth how compliance will be achieved and the milestones that will be used to reach this goal. The delay of implementation will be on the board's April agenda as an action item and stakeholders were requested to submit extension requests with implementation milestones to the executive officer by April 1, 2006. Many stakeholders expressed their commitment to implementing the E-pedigree requirement but noted the difficulty of meeting the 2007 compliance date and would present milestones to demonstrate their efforts, however, it was noted that some milestones might be difficult to achieve because they are dependent upon the actions of others in the distribution chain.

Adjournment

Chair Powers adjourned the Enforcement Committee – Workgroup on E-Pedigree at 2:45 p.m. He noted that the next meeting is scheduled for June 20, 2006, in Sacramento.

ATTACHMENT E

California State Board of Pharmacy
Citation and Fine Statistics
July 1, 2005 – April 17, 2006

512 citations have been issued this fiscal year

Total dollar amount of fines issued
$ 209,500.00

Total dollar amount of fines collected
$ 127,450.00*

*This amount only reflects payment of the citations issued this fiscal year.
Citations issued prior to this fiscal year have also been paid during this time period.

The average number of days from date case is opened until a citation is issued is **150**

Average number of days from date citation is issued to date citation is closed is **49**

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
512	96	8	93	106	53	35	14	1

Miscellaneous Citation Breakdown by license type

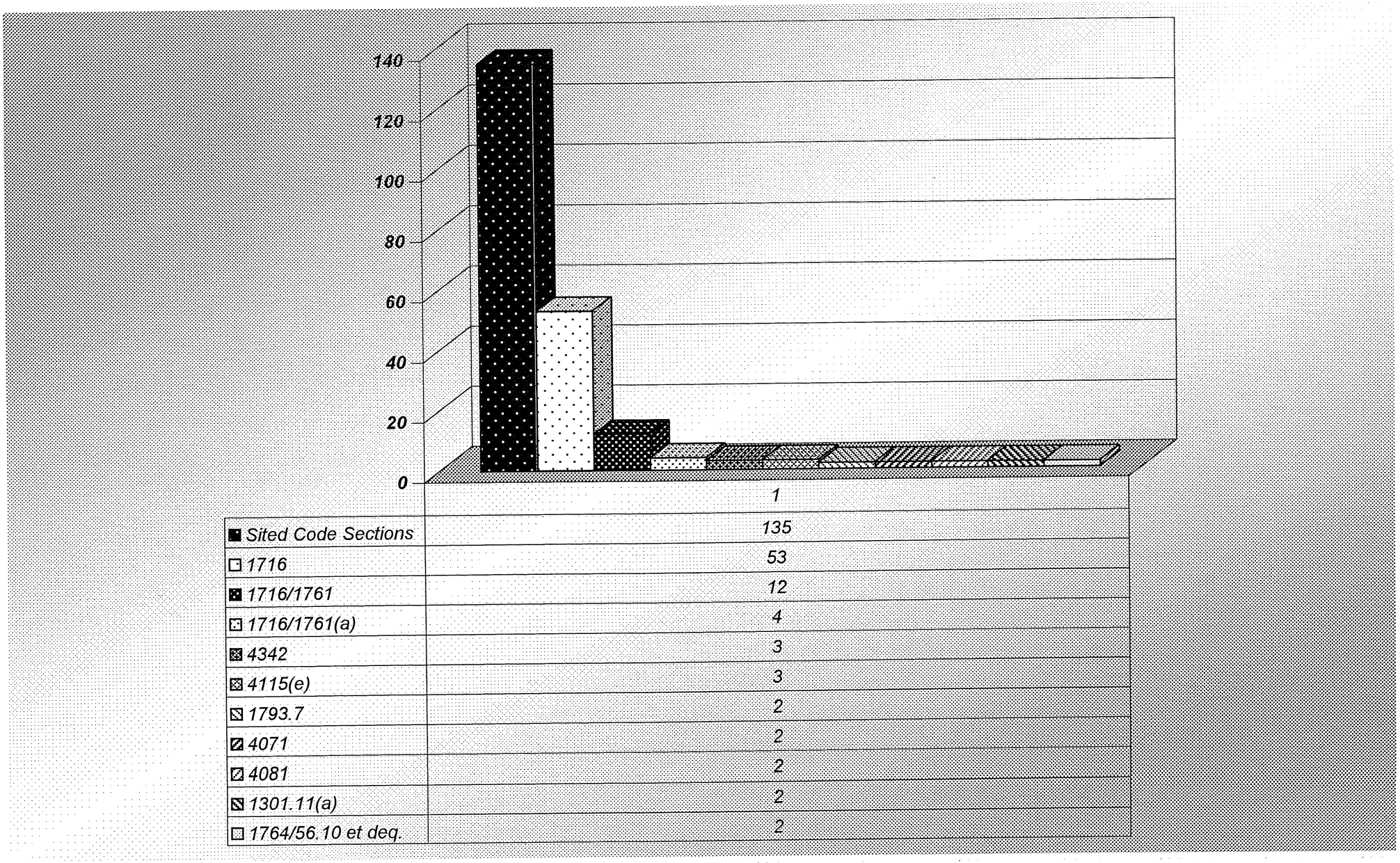
Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
45	31	2	2	5	14	4*	2	1

*Licensed Correctional Facilities, Exempt Pharmacies, and Vet Retailer

Top Ten Violations by license type from July 1, 2005 – April 17, 2006

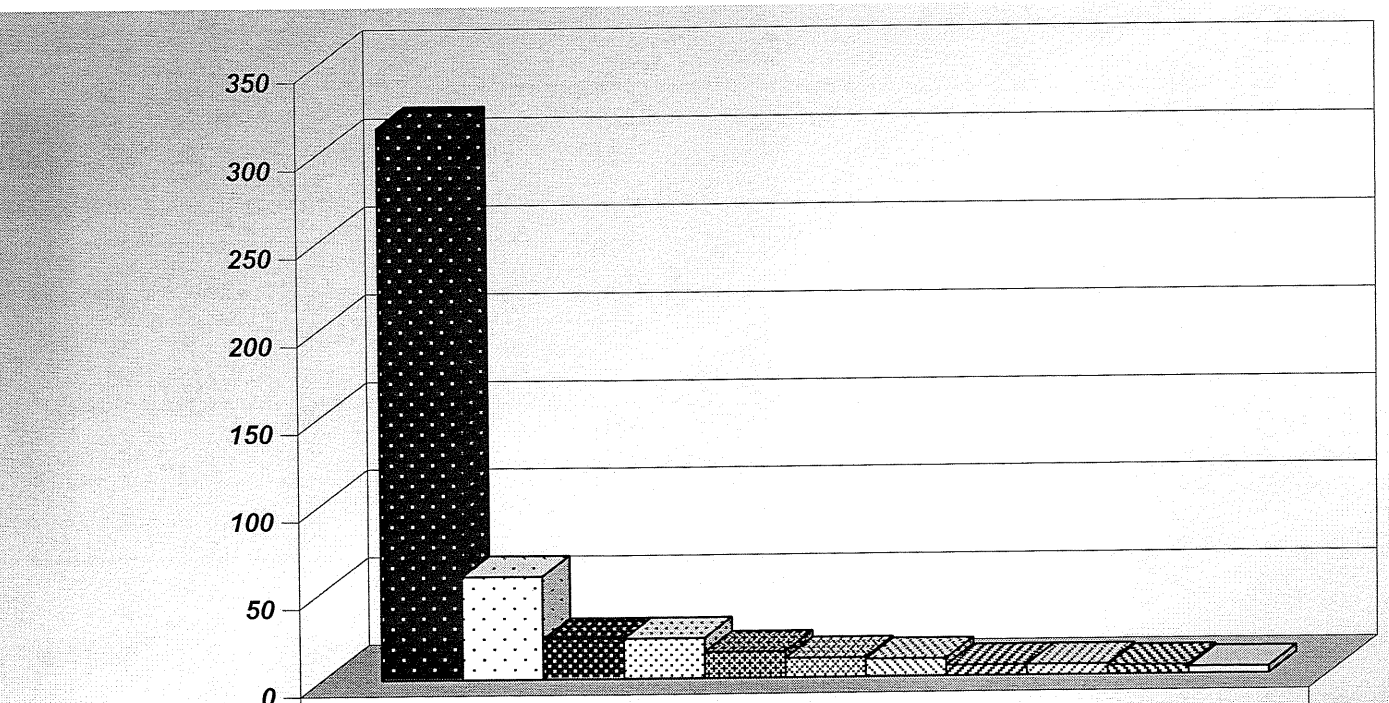
Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	40%	1716 - Variation from prescription	19%	1716 - Variation from prescription	7%
1716/1761 - Variation from Rx / Erroneous Rx	9%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	7.5%	4125/1711 - Quality assurance program	5.5%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	3%	1716/1761 - Variation from Rx / Erroneous Rx	7.5%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	5%
4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	2%	1715.6- Reporting drug loss	5%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	5%
4115(e) - Pharmacy technician license required	2%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	3.5%	4081/1718 - Records of dangerous drugs kept open for inspection/Current inventory defined	4%
1793.7 -Requirements for Pharmacies employing pharmacy technicians	1.5%	4125/1711 - Quality assurance program	3.3%	1716/1761 - Variation from Rx / Erroneous Rx	3%
4071 - Prescriber may authorize agent to transmit prescription; Schedule II excluded	1.5%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	2%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	2.5%
4081(a)- Records of dangerous drugs kept open for inspection	1.5%	4115(e) - Pharmacy technician license required	2%	1717(e) No licensee shall participate in any arrangement.., whereby medications may be left at, picked up from..., any place not licensed as a retail pharmacy.	3%
1301.11(a) - Persons Required to Register; Agents for Controlled Substances shall obtain DEA registration	1.5%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	1.6%	1717(f) – A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations § 1306.25...	3%
1764/56.10 et seq - Unauthorized disclosure of prescription and medical information	1.5%	1764/56.10 et seq - Unauthorized disclosure of prescription and medical information	1.3%	4059.5(b) -A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board.	3%

Top Ten Violation Codes for Pharmacist's, 104 Citations issued, 135 Codes Cited



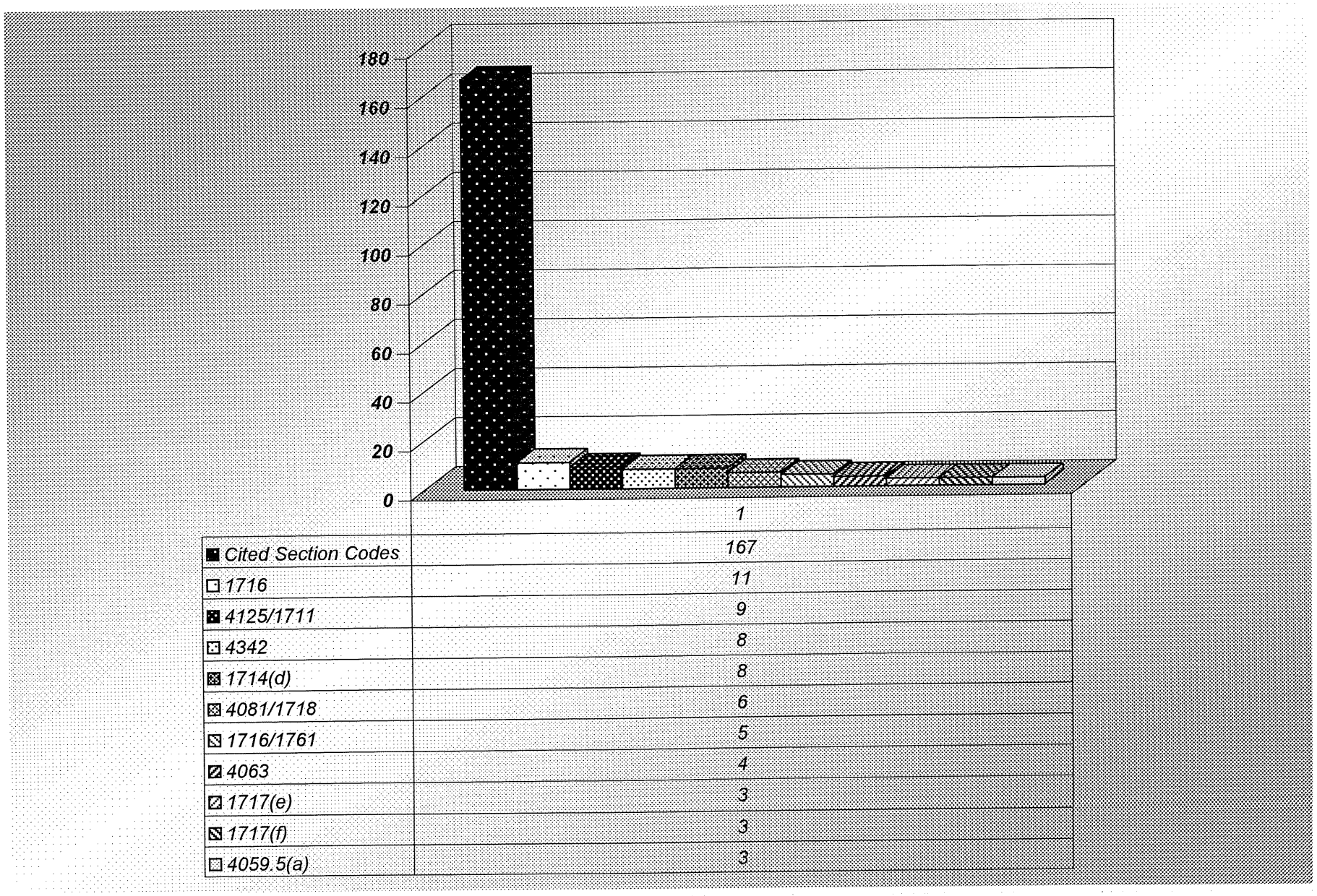
	1
Sited Code Sections	135
1716	53
1716/1761	12
1716/1761(a)	4
4342	3
4115(e)	3
1793.7	2
4071	2
4081	2
1301.11(a)	2
1764/56.10 et deq.	2

Top Ten Violations for Pharmacies, 199 Citations Issued, 315 Code Cited



	1
Cited Section Codes	315
1716	59
1714(b)	23
1716/1761	23
1715.6	15
4342	11
4125/1171	10
4063	6
4115(e)	6
1716/1761(a)	5
1764/56.10	4

Top Ten Violations for PIC's, 88 Citations Issued, 167 Codes Cited



	1
Cited Section Codes	167
1716	11
4125/1711	9
4342	8
1714(d)	8
4081/1718	6
1716/1761	5
4063	4
1717(e)	3
1717(f)	3
4059.5(a)	3

Board of Pharmacy Enforcement Statistics
Fiscal Year 2005/2006

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Complaints/Investigations					
Initiated	407	254	434		1095
Closed	548	408	410		1366
Pending (at the end of quarter)	637	587	683		683
Cases Assigned & Pending (by Team)					
Compliance Team	68	62	40		40
Drug Diversion/Fraud	85	70	72		72
Mediation Team	99	103	89		89
Probation/PRP	28	50	90		90
Enforcement	15	8	26		26
Application Investigations					
Initiated	37	10	5		52
Closed					
Approved	21	10	20		51
Denied	5	0	6		11
Total*	34	12	29		75
Pending (at the end of quarter)	46	53	25		17
Citation & Fine					
Issued	189	151	152		492
Citations Closed	153	137	134		424
Total Fines Collected	$56,236.00	$71,011.00	$83,386.00		$210,633.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2005/2006

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	49	34	16		73
Pleadings Filed	38	17	30		55
Pending					
Pre-accusation	64	76	60		76
Post Accusation	75	73	833		73
Total	160	161	152		161
Closed**					
Revocation					
Pharmacist	4	1	4		9
Pharmacy	1	1	2		4
Other	11	8	7		26
Revocation,stayed; suspension/probation					
Pharmacist	9	4			13
Pharmacy	1				1
Other					
Revocation,stayed; probation					
Pharmacist	5	2	1		8
Pharmacy	2				2
Other	1				1
Suspension, stayed; probation					
Pharmacist					
Pharmacy					
Other					
Surrender/Voluntary Surrender					
Pharmacist	1	1	2		4
Pharmacy					
Other	3	3	2		8
Public Reproval/Reprimand					
Pharmacist					
Pharmacy	1				1
Other					
Cost Recovery Requested	$120,408.25	$68,542.75	$127,302.00		$316,253.00
Cost Recovery Collected	$46,386.35	$64,815.08	$19,523.99		$130,725.42

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2005/2006

Workload Statistics

Probation Statistics

	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 05/06
Licenses on Probation					
Pharmacist	108	103	95		95
Pharmacy	16	14	11		11
Other	19	19	16		16
Probation Office Conferences	20	8	8		8
Probation Site Inspections	54	48	21		21
Probationers Referred to AG for non-compliance	3	3	0		6

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 03/31/06

Program Statistics					
In lieu of discipline	1	1	0		2
In addition to probation	5	4	1		10
Closed, successful	0	0	5		5
Closed, non-compliant	3	0	0		3
Closed, other	0	0	1		1
Total Board mandated Participants	47	51	49		49
Total Self-Referred Participants*	16	16	23		23
Treatment Contracts Reviewed	40	40	46		126

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of March 31, 2006.

Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were eighteen office conferences held so far this fiscal year

Number of requests	146
Number appeared	85

Number scheduled	146
Number Postponed	41*

*Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	19
Failed to appear	6

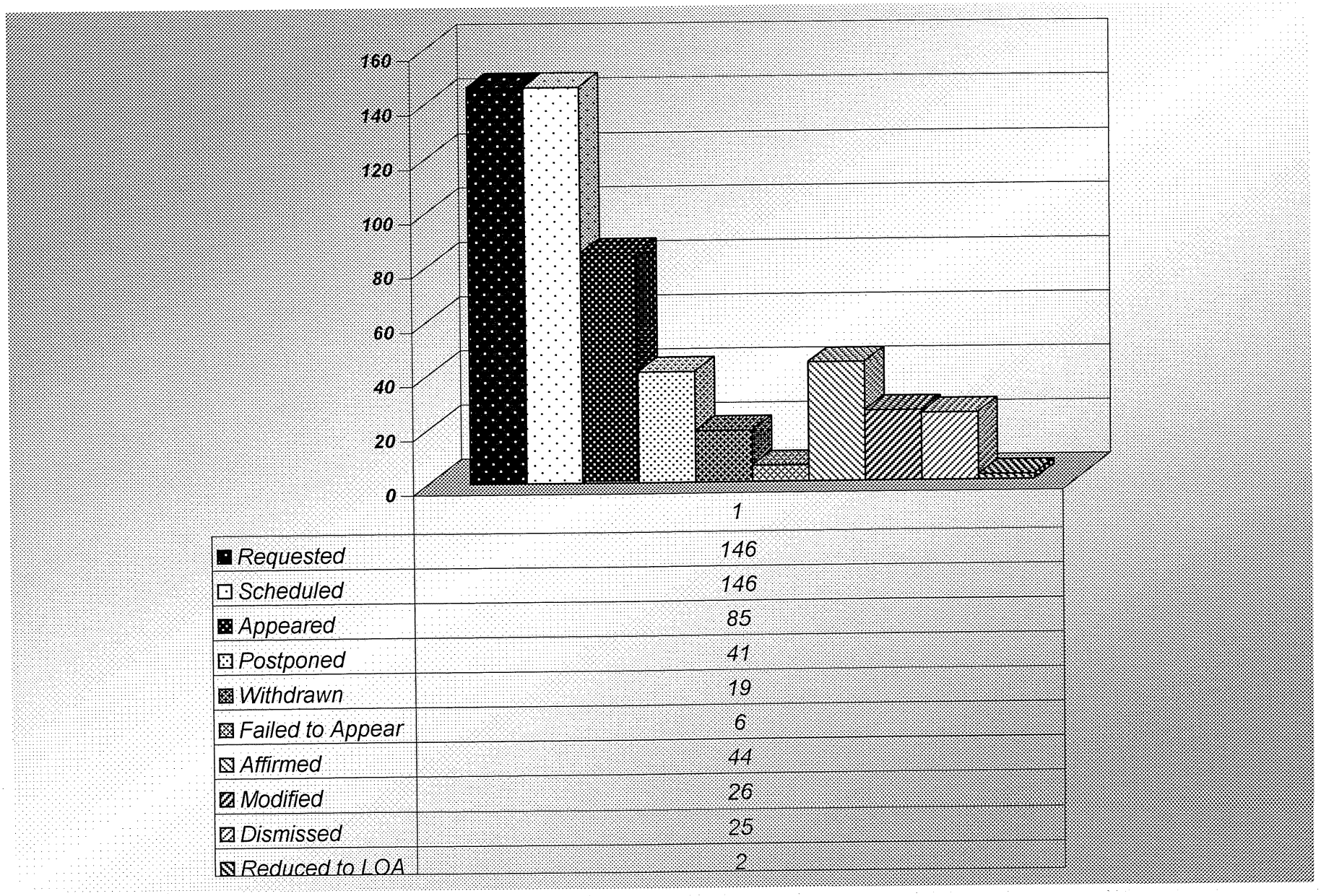
Office Conference results

Total number of citations affirmed	44

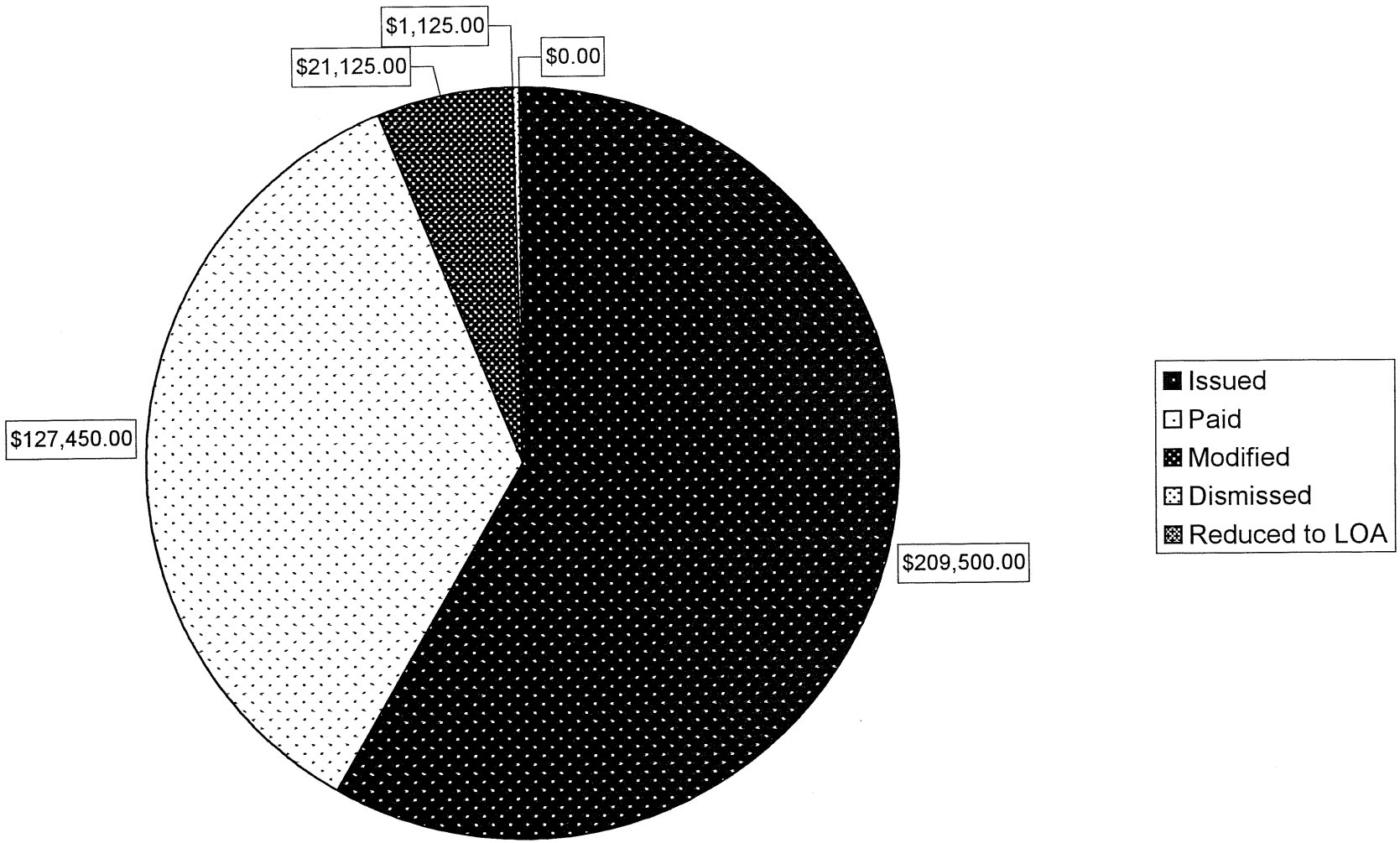
Decision	Total citations	Total dollar amount reduced
Modified	26	$21,125.00
Dismissed	25	$1,125.00
Reduced to Letter of Admonishment	2*	$0.00

*Both citations reduced to Letter of Admonishment, were citations issued without a fine

Board of Pharmacy Office Conference Statistics



Citation Dollar Totals for July 1, 2005 - April 17, 2006



ATTACHMENT F

Strategic Plan Status Report
Third Quarter 2005/2006
January 1, 2006 through March 31, 2006

Enforcement Committee

Goal 1: **Exercise oversight on all pharmacy activities**

Outcome: **Improve consumer protection**

Objective 1.1 **To achieve 100 percent closure on all cases within 6 months by June 30, 2006.**

Measure: Percentage of cases closed or referred within 6 months.

Task: **1. Mediate all consumer complaints within 90 days.**

Quarter 1: Based on **211** mediations/investigations sent to Supervising Inspectors for review.
Quarter 2: Based on **239** mediations/investigations sent to Supervising Inspectors for review.
Quarter 3: Based on **283** mediations/investigations sent to Supervising Inspectors for review.

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 90	24	11%	35	15%	8	3%		
91 to 180	11	5%	30	12%	18	6%		
181 to 365	1	0%	5	2%	28	10%		
366 and over	1	0%	0	0%	6	1%		

Task: **2. Investigate all other cases within 120 days.**

Review total stats same as above

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 120	106	50%	77	32%	131	46%		
121 to 365	63	30%	89	37%	91	32%		
366 and over	5	2%	3	1%	1	1%		

Task: **3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.**

Quarter 1: Based on **550** closed mediations/investigations.
Quarter 2: Based on **421** closed mediations/investigations.
Quarter 2: Based on **439** closed mediations/investigations.

Time Frame	Number/Percentage Per Quarter							
Number of Days	Q1		Q2		Q3		Q4	
0 to 180	405	74%	303	72%	244	56%		
181 to 365	123	22%	106	25%	164	37%		
366 to 730	18	3%	11	3%	30	7%		
731 and over	4	1%	0	0	1	0%		

Task:	**4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.** First, Second and Third Quarters: Nothing to report.
Task:	**5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports).** **CURES** **Number of pharmacies reporting to CURES and number of prescription records reported.** Pharmacies / Records Quarter 1: 5,044 / 2,799,811 Quarter 2: 5,680 / 3,440,267 Quarter 3: **5,212** / **3,239,285** **CURES reports provided to supervising inspectors and/or inspectors to aid in an investigation or inspection:** Quarter 1: 15 Quarter 2: 23 Quarter 3: **9** **CURES data used in complaint investigations:** Quarter 1: 20 Quarter 2: 8 Quarter 3: **0** **CURES compliance issues found in inspections:** Quarter 1: 10 Quarter 2: 25 Quarter 3: **8** **1782 Wholesaler Data Base:** No changes. Board has not been using 1782 reports for the last 3 to 4 years. **DEA 106 Theft/Loss :** Quarter 1: Approximately 42 investigations opened from DEA 106 loss reports. Quarter 2: Approximately 37 investigations opened from DEA 106 loss reports. Quarter 3: Approximately **88** investigations opened from DEA 106 loss reports.
Task:	**6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.** ▪ The CURES Users Group is scheduled to meet the 2nd Wednesday of every month to work on pharmacy noncompliance and data issues, share case information, as well as to improve database functionality. Additionally, the boards and DOJ have used these meetings to discuss issues and share information related to the implementation of SB 151 and more recently, SB734. Meetings were held November 13 and January 18.

BNE canceled the October meetings due to database issues. We do not meet in December.

First Quarter: During a recent driver upgrade to the new CURES web-based database, the BNE encountered a corruption to the front end portion of the database. The front end is the part of the database that allows users the ability to run standard and ad hoc queries and reports. None of the data was lost, only lost query and report functionality. While BNE is fixing the web-based system, they have temporarily reinstated the previous Impromptu CURES database to allow users access to the data and the ability to run queries and reports.

Second Quarter: The BNE completed repairs to the Web-based CURES system in December 2005. Board staff can now access CURES data through both the old and the new applications. BNE information technology staff are working with board staff to develop several automated standard reports using the new Web-based system's report-scheduling functionality, which will save staff time and provide monthly or weekly statistical and trend data via email automatically. Board staff is learning to use the new Web-based ad hoc reporting capabilities and will begin rebuilding CURES reports used regularly by the board for investigations and non-compliance. Reports that board staff developed in the old CURES database cannot be used on the new Web-based system. In the interim, the BNE is allowing access to CURES data through the old software to access the board's reports.

BNE has applied for federal grant money to fund additional improvements to CURES and allow BNE to meet new federal regulations (NASPER), such as capturing method of payment, and the legal identification of the patient or person picking up the controlled substance in CURES, the addition of Schedule IV controlled substance reporting and weekly reporting, etc. The DOJ is also studying ways to automate the process for physicians and pharmacists to request a patient activity report (PAR) from CURES. This will be especially useful for emergency room physicians and pharmacists. DOJ is also working on an automated reporting tool for direct dispensing physicians.

Third Quarter: The BNE continues working with board staff on developing standard CURES reports and data look-up functions. The BNE continues to study ways to automate CURES processes and implement NASPER federal requirements. Additionally, the BNE is working on the core language for the request for proposal (RFP) to conduct a feasibility study on real-time reporting to CURES and real-time data access to prescribers and pharmacists. Once the board receives this core language, staff will prepare the RFP and facilitate the proposal process.

Each Quarter: An inspector and a supervising inspector continue to participate on the monthly diversion task force meetings regarding the importation of dangerous drugs, repackaging and distribution in the U.S.; monthly Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego.

Task:	**7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.** First, Second, and Third Quarters: Nothing to report.
Task:	**8. Improve public service of the Consumer Inquiry and Complaint Unit.** First Quarter: ▪ Three new informational flyers were developed through UCSF addressing the issues of recalled medication, generic medication, and cutting drug costs. ▪ "What You Should Know Before Buying Drugs from Foreign Countries or the Internet" and "Tips to Save You Money When Buying Prescription Drugs", are now available in Chinese, Vietnamese, Spanish, and English languages. ▪ The board now has 24 consumer brochures and publications, including Health Notes. ▪ Board staff provided consumer information at the City of Sacramento Public Safety Center's Community Celebration on September 24, 2005. ▪ Board staff provided consumer information at the UCD Healthy Aging Summit on October 15, 2005. Second Quarter: ▪ Nothing to report this quarter. However, several events are scheduled for next quarter. Third Quarter: ▪ Six new informational flyers were developed through UCSF addressing the issues of double dosing, taking herbal medication, missing doses, Diabetes, disposing of medications, and oral health. ▪ Board staff developed 4 new consumer brochure: Easier to Read Prescription Drug Information; Children and Their Medications; Do You Sometimes Forget to Take Your Medications; and Medicare Part D. ▪ Board staff are revising several consumer brochures and fact sheets.
	9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. Investigative Activities: First Quarter: ▪ With the addition of Schedule III prescriptions added to the CURES database, the volume of data has grown too large to transmit to the inspectors via email. Staff developed a program to put on CD for each inspector that will automatically install an updated CURES data file to their laptops with the click of a button. CD's with updated CURES data files are mailed monthly to each inspector. ▪ To improve case management efforts, a monthly report is prepared and submitted to management. This report reflects the age of the case, who the case is assigned to, which cases are under review with the Supervising Inspector, cases that are referred to citation and fine and/or the Attorney General. The report identifies those cases not currently assigned. The report is also used as a tool to identify and locate those cases that have not had any recent activity. ▪ The department is currently evaluating tools to implement ad hoc reporting. Through the Enforcement Users Group meetings the latest information is that they are in the selection process and hope to be able to test the product soon. All vendor demonstrations are complete. The selection has not been announced. OIS has met with the Chief Information Officer and Project Executive Sponsor to

discuss findings. The CIO and PES will determine what further action will be taken.

- Staff performed various updates to improve functionality of the various enforcement databases.

Second Quarter: Nothing to report

Third Quarter:

- Staff performed ongoing improvements to Case Action Summary. Installed in March 2006.
- Staff developed instructional computer video clips - WinZip, Word, Excel, Expense Report, Screen Print, and Acrobat
- Staff indexed the 2006 Law Book
- Staff configured Supervisor Desktop Computers
- Staff and OIS installed encryption software on all laptops.

Inspection Activities – Automated inspection assignment status reports are sent to supervising inspectors weekly. Revisions and additions made to the automated inspection database include:

First Quarter:

- Color coding queries showing licensees that have already been scheduled for inspection, need to be scheduled for inspection, and those inspections completed had to be updated with new criteria now that the new 4 year inspection cycle has started.
- Revised wholesale and LSC automated reports to include assignment information.
- 75 security printers are currently approved to produce controlled substance prescription forms. 10 of the approved printers utilize the services of several hundred distributors that market their prescription products to prescribers.

Second Quarter:

- Staff developed a tool to print case action summaries.
- Staff developed a Probation / PRP database for staff and field inspectors. The system has been in the test mode for 3 months. Data entry of all participants and scanning of relevant documents is in the process.
- Staff set up and trained new inspectors on computers, cell phones, and GPS.
- CURES data is extracted monthly and integrated into the Inspector Data program allowing the Inspectors to view the total number of prescriptions by drug for a specific pharmacy during a three-month rolling cycle. Each month staff prepares a CD that contains a list of over 13, 000 inspection reports that can be viewed and printed; all active board-licensed California sites and licensees; DEA 106 list of scanned DEA 106 forms; and the CURES data file. The CD also provides other updates, when applicable, such as new issues of The Script and the new Pharmacy Law Book.
- Ongoing improvements to the Inspector Data and Inspector Activity installed in November 2005 and December 2006.
- Report functionality improvements to the Evidence database.
- Ongoing functionality and report capability improvements to the inspection assignment program.
- Staff copied inspector laptop data files and compared laptop Access data tables to the data tables on the server and made adjustments. Staff also generated missing inspection reports from inspector laptop files in electronic format and added to the server.
- SB734 transfers the application process for security printer approval to the Department of Justice January 1, 2006. Staff made changes to the database to provide greater functionality and ease in data entry before sending it to the DOJ. The board had approved 79 security printers as of January 1, 2006.

	Third Quarter: ▪ Ongoing improvements to Inspector Data and Inspector Activity. Updates installed in March 2006. Added Function to Print Receipts for a complaintant. ▪ Ongoing improvements to Assignment program function and reporting. ▪ Major changes to Inspector Probation Program - fixed transmission issues, added ability for multiple assignments for the same Participant, and added ability to type enter Interview forms. ▪ Monthly CD is sent to all inspectors and supervising inspectors with the following updated information: - View Word file - list of over 13,000 inspection reports that can be viewed/printed if connected to server - Teale Licensing File - all active licensed California business and licensees - CURES Data file - approximately 150,000 records per 3 month period. - Contains summarized data for a pharmacy - DEA 106 file - list of scanned DEA 106 Theft or Loss forms received. Can be viewed if online
Objective 1.2	**To achieve 100 percent closure on all administrative cases within one year by June 30, 2006.** **Measure:** Percentage closure on administrative cases within one year.
Task:	1. **Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases.** ▪ First Quarter: DAG costs increase to $139 per hour. Board receives supplemental funding of $216 thousand to purchase the same level of AG services at a higher hourly rate. ▪ Second Quarter: Nothing to report. ▪ Third Quarter: DAG rates will increase to $158 per hour and paralegal rates will increase to $101 per hour effective July 1, 2006.
Task:	2. **Aggressively manage cases, draft accusations and stipulations, and monitor AG billings and case costs.** ▪ Case management and review of pending cases is a continuous process.

	Q1	Q2	Q3	Q4
Status memos sent to AG	35	24	**10**	
Disciplinary Cases Closed:				
0-365 days	21	11	**11**	
366 + days	21	11	**10**	
Accusations reviewed	39	25	**36**	
Accusations needing revision	7	3	**6**	
Accusations filed	38	17	**30**	
Stips/proposed decisions reviewed	15	19	**14**	
Cases reviewed for costs	10	8	**7**	

Task:	3. **Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances.** First, Second, and Third Quarters: Nothing to report.
Task:	4. **Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.** ▪ Administrative Case Management Database Program: First, Second, and Third Quarters: No changes.
Objective 1.3:	**Inspect 100 percent of all licensed facilities once every 3 to 4 years by June 30, 2009.** **Measure:** Percentage of licensed facilities inspected once every 3 years.
Task:	1. **Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.** ▪ For all quarters, see response to Objective 1.1, Task #9
Task:	2. **Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.** **Inspection Statistics Background:** First Quarter: On July 1, 2005, the board began its second 3 to 4-year cycle of inspections towards the goal of inspecting all sites once every 3 to 4 years (by June 30, 2009): ▪ Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,735**; · Total number of inspections completed **611**, · Total number of inspections to be completed by June 30, 2009 are **7,119 or 7.9%**. ▪ Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **7,915**; · Total number of inspections completed **618** or **7.8%.** · Total number of inspections to be completed are **7,292** *inspection data as of 10/1/05 Second Quarter: ▪ Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,670**; · Total number of inspections completed **1.202 or 15.67%;** · Total number of inspections to be completed by June 30, 2009 are **6,464.** ▪ Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **7,947**;

- Total number of inspections completed **1,227** or **15.44%;**
- Total number of inspections to be completed are **6,716.**

*inspection data as of 1/1/06

Third Quarter:

- Total number of locations identified to inspect from those licensed as of July 1, 2005 (does not include sites licensed after 7/1/05) to meet the board's goal of inspecting all sites once every 3 to 4 years was approximately **7,583**;
  - Total number of inspections completed **1,671 or 22.04%;**
  - Total number of inspections to be completed by June 30, 2009 are **5,908.**

- Total number of locations identified to inspect (including sites licensed before and after 7/1/2005) was approximately **7,993**;
  - Total number of inspections completed **1,739 or 21.76%;**
  - Total number of inspections to be completed are **6,250.**

*inspection data as of 4/3/06

Total Number	**Q1**	**Q2**	**Q3**	**Q4**
Inspections Completed	710	568	**807**	
Routines/ Wholesaler-Vet-Retailer/ Probation/PRP	584	463	**723**	
Sterile Compounding *(included in routines)*	79	36	46	
Investigation Inspections	126	105	**142**	
Status 3 *(included in routines)*	4	9	7	
Routine resulting in complaint investigation. (included above)	34	14	26	

Wholesaler/Vet Retailer Inspection Program – The board implemented the Wholesaler Inspection Program beginning March 1, 2005. Data are included in the previous table and shown separately here for reference only.

A total of **506** sites identified for inspection.

- As of September 30, 2005, the Diversion Team has completed a total of 239 inspections since program inception.
- As of January 1, 2006, the Diversion Team has completed a total of 285 inspections since program inception.
- As of April 1, 2006, the Diversion Team has completed a total of **304** inspections since program inception.

	Q1	**Q2**	**Q3**	**Q4**
Wholesaler/Vet Retailer Inspections Completed *	95	52	**87**	

* Includes routine, call backs, and CI inspections.

Task:

3. Seek legislation to mandate that periodic inspections be done on all board-licensed facilities

First, Second, and Third Quarters: Nothing to report.

Objective 1.4	**Develop 4 communications in addition to the inspections program to educate board licensees by June 30, 2006.** **Measure:** Number of communication venues (excluding inspection program)
Task:	**1. Develop the board's website as the primary board-to-licensee source of information.** ▪ Public disclosure of disciplinary history on licensees is online. First Quarter Web Additions/Revisions ▪ Posted board meeting dates for 2006 ▪ Posted board and committee information - agenda, materials & minutes ▪ Regulation updates ▪ Updated several application packets ▪ Added new version of self-assessment forms ▪ Created a page on Hurricane Katrina Information and Resources ▪ Added newly approved Security Printers (total 77) ▪ Updated the Script Newsletter Index ▪ Sent out subscriber alert notifications to the board's e-mail notification list Second Quarter Web Additions/Revisions: ▪ Updated all Web pages with the board's new address and phone numbers. ▪ Added bond information to applications. ▪ Sent subscriber alerts. ▪ Update the regulation and legislation Web pages. ▪ Posted board and committee meeting agendas and materials. ▪ Updated the strategic plan. ▪ Revised the security printer Web page to link to the DOJ. ▪ Added the revised community, hospital, and sterile compounding self-assessment forms. Third Quarter Web Additions/Revisions: ▪ Updated security printer information and links ▪ Updated instructions for some of the application packets ▪ Updated the law book ▪ Updated CPJE regrade information ▪ Added the new *The Script* newsletter ▪ Added Appstatus@dca.ca.gov email address for Pharmacy Tech applicants to check status of their application. ▪ Corrected law book contents ▪ Added contact information to the website ▪ Posted board and committee meeting agendas and materials ▪ Sent out subscriber alert notifications to the board's e-mail notification list
Task:	**2. Prepare two annual *The Scripts* to advise licensee of pharmacy law and interpretations.** ▪ January 2005 *The Script* Newsletter published. ▪ October 2005 *The Script* Newsletter published. ▪ January 2006 *The Script* Newsletter published. ▪ The next *The Script* is scheduled to be published in July 2006.
Task:	**3. Update pharmacy self-assessment annually.** First Quarter: Revised form so that fields can be filled in online. New version posted of the web

	▪ Regulation requiring 2005 version took effect 10/7/05. Second Quarter: Board approved the wholesale self-assessment October 2005 and recommends moving ahead with regulations to require wholesalers to complete a self-assessment every 2 years. Third Quarter: Nothing to report
Task:	**4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.** First Quarter CE Presentations ▪ Supervising Inspector Nurse presented information about the board and how it investigates cases to a group of United States Attorneys on July 20. ▪ Supervising Inspector Nurse participated in a training module for federal investigators who will be monitoring fraud in the Medicare Prescription Drug Plan programs in San Diego on September 20. ▪ The board staffed a public information booth the City of Sacramento Public Safety Public Fair on September 24. ▪ The board will staff a public information booth on October 15 at the UCD Healthy Aging Fair. ▪ Supervising Inspector Ratcliff will present information on pharmacy law changes at a UFCW-Orange County Pharmacist Association continuing education conference on October 16. ▪ The board will staff an information booth at CSHP Seminar on October 21 and 22. ▪ Several board members will present information at this association meeting. ▪ Supervising Inspector Ming will present information about pharmacy law to a group of UCSD pharmacy students in mid-November ▪ Assistant Executive Officer Herold will present information about the board to a group of UCSD pharmacy students on November 28. ▪ Supervising Inspector Ming will present information about sterile compounding to a group of pharmacy technician students at Santa Ana College on November 30. ▪ Board Member Jones will present information about pharmacy technology at the NABP Fall Conference in December. Second Quarter CE Presentations: ▪ Supervising Inspector Nurse participated as the board's representative to the Northern California Pain Initiative on January 9. ▪ Board President Goldenberg participated on an NABP Task Force on Telepharmacy and the Implementation of the Medicare Drug Benefit Medication Therapy Management Provisions conference call on October 27. ▪ Board President Goldenberg was keynote speaker at a conference of long-term care executives on Medicare Part D in Los Angeles on November 4. ▪ Supervising Inspector Ming presented information about pharmacy law and board pharmacy inspections to a group of UCSD pharmacy students on November 14. ▪ Assistant Executive Officer Herold presented information about the board to a group of UCSD pharmacy students on November 28. ▪ Supervising Inspector Ming presented information about sterile compounding to a group of pharmacy technician students at Santa Ana College on November 30. ▪ Board Member Jones presented information about pharmacy technology at the NABP Fall Conference in Florida on December 4. ▪ Board Member Fong presented information about new pharmacy laws to pharmacists at the Diablo Valley Pharmacists Association Meeting on December 28. ▪ Supervising Inspector Ratcliff presented information to the California State University Pharmacists on current law topics on January 12. ▪ Board President Goldenberg and Supervising Inspector Ratcliff presented information

	about the board and new pharmacy law on January 19 to USC students. Third Quarter CE Presentations: ▪ Executive Officer Harris participated as a speaker during the Federation of Associations of Regulatory Boards annual meeting in early February, as part of a panel discussion on "Board Governance: A Panel Discussion on the Pros and Cons of Different Board Structures" on February 3. She also participated in a panel discussion on February 5 on alternative enforcement models. ▪ Executive Officer Harris and Analyst Sue Durst staffed an information booth at the San Diego Consumer Protection Day fair on February 3; approximately 1,500 people attended. ▪ Supervising Inspector Nurse provided a PowerPoint presentation via teleconference to an FDA Counterfeiting Task Force in Bethesda, MD, on February 9. ▪ The board staffed an information booth at the CPhA Outlook Meeting on February 17 and 18. ▪ Supervising Inspector Ming and Exam Analyst Debbie Anderson provided law and examination information to 80 Western Pharmacy School students on February 24. ▪ Supervising Inspector Ratcliff provided information about pharmacy law to 125 students at UCSF on February 28. ▪ Board Member Ruth Conroy spoke to 50 Touro University pharmacy students on board legislative issues on March 31. ▪ Supervising Inspector Ming presented law review information to UCSF's 4th year students on April 7. ▪ Board President Goldenberg provided welcoming remarks to the opening session of the National Association of Boards of Pharmacy Annual Meeting in San Francisco. Other board presentations at this annual meeting included moderation of a panel discussion by Executive Officer Harris on emergency preparedness and a poster session on the Notice to Consumers that must be displayed in pharmacies.
Task:	**5. Hold quarterly Enforcement Committee Meetings** First Quarter: ▪ Meeting held June 2005. Discussed importation, use of automated devices in clinics. Interpretation of pharmacy law related to Interns, waiver requests for self-use automated delivery systems, and petitions for consideration. ▪ Meeting held September 2005. Discussed importation, disciplinary guidelines, self assessment for wholesalers, legibility of prescriptions, DEA requirements for prescribing Schedule II drugs, new labeling requirements, and electronic pedigree requirements. Second Quarter: ▪ Meeting held in December 2005. Discussed implementation of pedigree requirement, faxed prescription form patients, generic substitution by prescriber on electronic data transmission prescriptions, citation and fine program, GAO report on anabolic steroid without prescription, and importation of prescription drugs. Third Quarter: ▪ Meeting held in March 2006. Discussed implementation of E-pedigree requirements, E-pedigree standards, and E-pedigree pilot programs. Facilitated an E-pedigree questions and answers session, and discussed request to extend E-pedigree implementation to January 2008.

Objective 1.5	**To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2006.** **Measure:** Percentage compliance with program requirements

Task:

1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program).

Pharmacists Recovery Program	**Q1**	**Q2**	**Q3**	**Q4**
Total # of PRP Participants	63	67	**67**	
Number Referred to PRP	6	5	**1**	
Number Closed from PRP	4	0	**6**	

Probation Monitoring Program - Number on Probation	**Q1**	**Q2**	**Q3**	**Q4**
Pharmacists	108	103	**95**	
Pharmacies	16	14	**11**	
Other	19	19	**16**	

Citation and Fine	**Q1**	**Q2**	**Q3**	**Q4**
Citations Issued	189	151	**152**	
Fines Collected *	$56,236	$71,011	**$83,386**	

* Data for fines collected has been updated for all quarters.

Task:

2. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.

First Quarter: Currently in the process of establishing a database for the Citation and Fine unit. The database will automate the processes of creating letters, memos and statistics, which are currently completed by staff manually.

- Working with staff in linking databases
- Working with OIS to automatically receive monthly licensure information
- Working with Citation and Fine unit to verify needs for letters and memos
- Testing for integrity of statistical data

Second Quarter: No changes.

Third Quarter: No changes

Objective 1.6	**Respond to 95 percent of all public information requests within 10 days by June 30, 2006.** **Measure:** Percentage response to public information requests within 10 days.
Task:	**1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions.** ▪ Web Enforcement Look-Up – In production May 2004. Completed disciplinary actions are entered into the database on an on-going basis. ▪ Staff has begun scanning public disciplinary documents for availability as a PDF document on the Web Enforcement Look Up. ▪ March 2006 - Public documents from 2001 to current are now available for download into PDF format online.
Task:	**2. Establish on-line address of record information on all board licensees-** ▪ Licensee address of record information became available on-line to public in December 2003. ▪ Regulation to ban posting on Website the address of record of intern pharmacists goes to the board for adoption. If approved, the rulemaking files will be submitted to the Administration for approval in November 2005. ▪ Regulations are anticipated to go into effect in the summer of 2006.
Task:	**3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests.**

Total by Type of Requests Received								
Request Type	**Q1**		**Q2**		**Q3**		**Q4**	
Public	30		17		**27**			
Licensees	24		7		**9**			
Other agencies	29		34		**43**			
License Verifications	223		200		**138**			
Time Frame Records Requests Responded To	**Q1**		**Q2**		**Q3**		**Q4**	
	Number and Percentage Per Quarter							
Within 10 days	67	81%	38	66%	**49**	**62%**		
Over 10 days	16	19%	20	34%	**30**	**38%**		
Time Frame License Verifications Responded To	**Q1**		**Q2**		**Q3**		**Q4**	
	Number and Percentage Per Quarter							
Within 10 days	210	94%	176	88%	**126**	**91%**		
Over 10 days	13	6%	24	12%	**12**	**9%**		

Objective 1.7	**Initiate policy review of 25 emerging enforcement issues by June 30, 2006.** **Measure:** The number of issues.
Tasks (Issues)	1. Reimportation of drugs from Canada. ▪ Importation of Drugs - 2004: discussed at every Enforcement Committee meeting and

board meeting.
- January 2005: Discussed at Board Meeting.
- March 2005: Discussed at Enforcement Committee Meeting.
- April 2005: Discussed at Board Meeting.
- May 2005: Discussed at Enforcement Committee Meeting.
- July 2005: Discussed at Board Meeting.
- September 2005: Discussed at Enforcement Committee Meeting.
- October 2005: Discussed at Board Meeting
- December 2005: Discussed at Enforcement Committee Meeting
- Februrary 2006: Discussed at Board Meeting

2. Modification to the Quality Assurance Regulation regarding patient notification. (completed)
3. Proposals regarding wholesale transactions.
   - Sponsored legislation (SB 1307).
   - January 2005 – SB 1307 became effective.
   - January 2005– Participated in NABP Task Force to develop e-pedigree elements.
   - January 2005 – Participated in NABP Wholesaler's Distributors Regulatory meeting and participated in NABP Task Force to develop e-pedigree elements.
   - February 2005 –Implementation of SB 1307.
   - April 2005– Presentation to board on pedigree software
   - June 2005 – two presentations to Enforcement Committee on pedigree software.
   - September 2005– discussed at the Enforcement Committee Meeting regarding the difficulty of implementation.
   - November 2005: Recommend legislation clean-up language for 2006.
   - December 2005: Developed Q & A for implementation discussion at the Enforcement Committee Meeting.
   - February 2006: Board agreed to form workgroup to discuss implementation
   - March 2006: First workgroup meeting held with over 65 participants.
4. Clarification regarding prescription records by authorized officers of the law.
   - October 2005: updated article in the board's newsletter.
5. Review of Pharmacy Law regarding the delivery of medications after the pharmacy is closed and a pharmacist is not present.
   - Sponsored legislation SB 1913
   - January 2005– bill passed, SB 1913 effective
6. Off-site order entry of hospital medication orders (Bus. & Prof. Code Section 4071.1).
   - DOJ and board approved for controlled substances.
7. Prescriber dispensing.
   - May 2003 - Workgroup with Medical Board on proposal on prescriber dispensing by physician groups.
8. Implementation of federal HIPAA requirements.
9. Prohibition of pharmacy-related signage.
10. Implementation of enforcement provisions from SB 361.
11. Implementation of SB 151 (elimination of the Triplicate).
    - January 2005 – new changes to controlled substance law took effect. Continued CE presentations.
    - February 2005 – continued CE presentations
    - March 2005 – discussed Q & A at Enforcement Committee meeting.
    - April 2005 – discussed at board meeting.
    - June 2005 – discussed at Enforcement Committee meeting.
12. Dispensing non-dangerous drugs/devices pursuant to a prescriber's order for Medi-Cal reimbursement
13. Authorized activities in a pharmacy.
14. Review of Quality Assurance Program.
15. Limited distribution and shortage of medications.
16. Conversion of paper invoices to electronic billing.

17. Automated dispensing by pharmacies.
18. Public disclosure and record retention of substantiated complaints.
19. Evaluation of QA regulation
20. Biometric technology
    - Statutory change (SB 1913), regulation proposal to implement.
    - October 2005 - Regulation became effective.
21. Update of pharmacy laws related to PRP.
    - October 2004–board approved statutory changes.
    - February 2005 – Legislation introduced – SB 1111.
    - January 2006: Statutory change (SB111) became effective.
22. Update of pharmacy law related to pharmacy technicians.
    - October 2004–board approved statutory changes.
    - February 2005 – Legislation introduced – SB 1111.
    - January 2006: Statutory change (SB111) became effective.
23. Clean-up of "Letter of Admonishment" provision.
    - October 2004–board approved statutory changes.
    - February 2005 – Legislation introduced – SB 1111.
    - January 2006: Statutory change (SB111) became effective.
24. Use of "kiosks: for drop-off of prescriptions.
    - October 2005– board approved waiver for kiosks and regulation change
    - October 2005: Board held regulation hearing – regulation tabled.
    - December 2005: Proposed regulation withdrawn
    - January 2006: Revised language to be considered by Legislation and Regulation Committee.
    - February 2006: Board approved revised language and moved to regulation hearing.
25. Use of self-services dispensing units for pick-up of refill prescriptions.
    - October 2004– board approved statutory changes
    - January 2005– board approved second waiver
    - April 2005 – board approved third waiver in conjunction with a study.
    - June 2005– request to require "Pharmacy Service Plans" for approved waiver.
    - July 2005Board approved two more waivers.
    - Overview of study by UCSD presented.
    - September 2005 - Regulation change noticed.
    - October 2005: Board held regulation hearing – regulation tabled.
    - December 2005: Proposed regulation withdrawn
    - January 2006: Revised language to be considered by Legislation and Regulation Committee.
    - February 2006: Board approved revised language and moved to regulation hearing.
26. Mandatory reporting of impaired licensees.
    - January 2005–board approved statutory change
    - March 2005 - SB 1111 introduced
    - January 2006: Statutory change (SB111) became effective.
27. Electronic Prescribing Standards for the implementation of the Medicare Drug Improvement and Modernization Act (MMA) of 2003.
    - March 2005 – Discussed at Enforcement Committee meeting – no action necessary.
28. Prescribing Authority for Naturopathic Doctors
    - February 2005 – Met with Bureau of Naturopathic Doctors and other interested parties regarding proposed legislative changes to address inconsistencies in pharmacy law.
    - February 2005 – Requested legal opinion from DCA.
    - April 2005 -Opinion provided to Board.
    - June 2005 -Clean-up statutory provisions introduced in bill.
    - December 2006: Requested presentation from Naturopathic Doctor on profession practices.
29. Pharmacy law clarification regarding pharmacist interns, orally and electronically transmitted prescriptions, and filling on non-security Rx form for controlled substances. (June 2005)

	30. Use of automated drug delivery systems in clinics. (June 2005) ▪ July 2005: Board clarified use of systems 31. Request to repeal CCR 1717.2. ▪ July 2005 Board approved – Referred to Legislation and Regulation Committee. 32. Legal requirements and process for Petitions for Reconsideration. (June 2005) ▪ July 2005: Board reaffirms the process for petition for reconsideration. 33. Proposed self-assessment for wholesalers. (September 2005) ▪ October 2005: Board approved proposed regulation to implement self-assessment form for wholesalers – Referred to Legislation and Regulation Committee. 34. Legibility of prescription – Refer to SCR49 Medication Error Panel for review. (Sep 2005) 35. Revised self-assessment for pharmacies. ▪ October 2005 - Regulation became effective. 36. Update regulation 1745 regarding the partial fill of Schedule II prescriptions. ▪ October 2005 - Regulation change became effective. 37. Proposal to amend B & P Code section 4040 (c) to allow a pharmacy to accept a fax prescription from a patient. ▪ December 2005: Discussed at Enforcement Committee Meeting and will be referred to the board. ▪ February 2006: Pharmacy can accept a faxed prescription from a patient but cannot dispense the medication until the prescription is received. No law change is necessary. 38. Proposal to amend B & P 4073(b) to indicate the prohibition on generic substitution by a prescriber on an "electronic data transmission" prescription. ▪ December 2005: Discussed at Enforcement Committee Meeting and will be referred to the board. ▪ February 2006: Board approved. Will be added to Omnibus bill. 39. Reviewed citation and fine program at the request of California Retailers Association ▪ September 2005: Noticed on agenda and provided 3-yar data on program – no comments were received. ▪ December 2005: Noticed on agenda and provided 3-yar data on program – no comments were received. 40. Revised Disciplinary Guidelines ▪ September 2005: Discussed at Enforcement Committee Meeting ▪ October 2005: Board approved the changes for a proposed amendments to the regulation – referred to the Legislation and Regulation Committee.